UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Proposed Rule, National Emission Standards for Hazardous Air Pollutants: Hydrochloric Acid Production Residual Risk and Technology Review, 84 Fed. Reg. 1570 (Feb. 4, 2019); 84 Fed. Reg. 8069 (Mar. 6, 2019).	Docket No. EPA-HQ-OAR-2018-0417

COMMENTS OF BLUE RIDGE ENVIRONMENTAL DEFENSE LEAGUE, CALIFORNIA COMMUNITIES AGAINST TOXICS, COMING CLEAN, ENVIRONMENTAL JUSTICE HEALTH ALLIANCE FOR CHEMICAL POLICY REFORM, LOUISIANA BUCKET BRIGADE, LOUISIANA ENVIRONMENTAL ACTION NETWORK, NATURAL RESOURCES DEFENSE COUNCIL, OHIO VALLEY ENVIRONMENTAL COALITION, SIERRA CLUB, AND EARTHJUSTICE

Submitted via regulations.gov and e-mail on April 26, 2019 by Earthjustice

Earthjustice submits these comments on behalf of the above-listed environmental and community groups ("Commenters") whose members and constituents live and work – and whose children play and attend school – near industrial facilities across the United States that are sources regulated by this rulemaking, including Hydrochloric Acid Production and collocated sources at the same facility, and other sources that emit ethylene oxide. For the reasons provided herein, Commenters urge EPA to set stronger air toxics emission standards for these facilities to bring relief to the more than 16 million Americans living near these sources of toxic air pollution.

INTRODUCTION AND SUMMARY

The Clean Air Act charges the U.S. Environmental Protection Agency (EPA) with protecting public health and the environment from the toxic air pollution of industrial sources located in and near neighborhoods where Americans live, work, and go to school. A bipartisan Congress enacted the 1990 Amendments of the Clean Air Act to prevent cancer and reduce other serious health effects from toxic air pollution, and to do so especially in communities overburdened by such pollution.[1] President George H.W. Bush signed these Amendments into law. In this rulemaking, EPA must fulfill all legal responsibilities under 42 U.S.C. § 7412(d) and § 7412(f) by reducing toxic air pollution which creates preventable health threats.

Stronger emission standards for HCl facilities are long overdue. Sections 112(d)(6) and (f)(2) of the Clean Air Act require EPA, within eight years after first setting standards for a source category, to perform a technology and community health risk review and set updated standards as the Act directs.[2] EPA first promulgated air toxics emission standards for these sources under 42

[1] S. Rep. No. 101-228, at 128-29 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3385, 3513-14.
[2] 42 U.S.C. § 7412(d)(6), (f)(2).

U.S.C. § 7412(d) in 2003.[3] Had EPA timely fulfilled its risk and technology review obligation, it would have completed its first round of review and rulemaking updates by 2011, and would be performing the next required technology review this year. Instead, in 2019, EPA is only now completing its first risk and technology review *more than 8 years overdue*. EPA is only performing these rulemakings at all because a federal court ordered EPA to do its job, setting a new deadline for EPA to act and remedy its violations of the law.[4] EPA is also on statutory or court-ordered deadlines for other source categories that are collocated with HCl facilities, such as other chemical manufacturing sources.[5] Arbitrarily, EPA has decided to issue the HCl proposal before the proposal for collocated sources. Rather than delay action for collocated sources, as it proposes to do, it must exercise its full authority to protect public health. EPA has full authority and ability to coordinate its chemical manufacturing rulemakings so that it properly addresses and reduces the cancer and other health risks for people facing the combined or cumulative impact of the pollution from all of these collocated sources.

Hydrochloric acid facilities expose Americans to toxic air pollution that harms their health, welfare, and way of life. There are 19 major sources regulated by the HCl production standard, and most are sited and operated at the same facility with other regulated major sources of toxic air pollution. 84 Fed. Reg. at 1588. According to EPA's Risk Assessment, the existing sources in this source category emit 72 (tons per year or tpy) of air toxics, including 50 tpy of hydrochloric acid (HCl), and 22 tpy of chlorine (Cl2).[6] These industrial facilities, including collocated sources at contiguous locations "under common control," also release other toxic pollution, such as the potent carcinogens ethylene oxide (EtO) and trichloroethylene (TCE), into communities' air.

EPA finds that HCl sources cause an increased risk of chronic harm to the respiratory system of 2 (hazard quotient or HQ), based on allowable emissions of chlorine, which is *two times higher* than the threshold at which harm occurs; and an acute risk of at least 0.7 due to HCl – and as high as an HQ of 42.[7] All of EPA's risk numbers are likely to be significant underestimates because of the many ways in which EPA's residual risk assessment fails to follow the best available science, as discussed below.

EPA also finds that a majority of these sources are collocated with sources at the same facility, and together cause an extremely high amount of cancer risk – as high as 600-in-1 million, or over six times the level (100-in-1 million) that EPA deems *presumptively unacceptable*.[8] EPA found that HCl facilities cause "one excess case [of cancer] every 11 years." 84 Fed. Reg. at 1583. EPA estimates that 980,000 people experience additional cancer risk due to these facilities. *Id.* In

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[3] HCl National Emission Standards for Hazardous Air Pollutants ("NESHAP"), 68 Fed. Reg. 19,076 (Apr. 17, 2003), https://www.govinfo.gov/content/pkg/FR-2003-04-17/pdf/03-5517.pdf.
[4] *Cal. Communities Ag. Toxics et al. v. Pruitt*, 241 F. Supp. 3d 199 (2017).
[5] EPA, Risk and Technology Review (last updated Apr. 18, 2019), https://www3.epa.gov/airtoxics/rrisk/rtrpg.html.
[6] EPA, Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the 2018 Risk and Technology Review Proposed Rule ("HCl RRA") at 35 (Dec. 2018), EPA-HQ-OAR-2018-0417-0027, https://www.regulations.gov/EPA-HQ-OAR-2018-0417-0027.
[7] *Id.*
[8] HCl RRA at 6.

addition, these facilities cause a facility-wide target organ-specific hazard index (TOSHI) of 6, which is *six times* the level at which harm is known to occur (1). *Id.* These threats include: harm to the kidney, immunological, developmental, neurological, reproductive, and liver hazard indices. *See* HCl RRA at 6-7.

EPA's own demographic analysis shows disproportionate exposure and resulting health impacts for racial minorities, for Blacks (or African Americans), and for low-income people compared to their representation in the national population. 84 Fed. Reg. at 1583. The toxic air pollution to which people are exposed from these sources and resulting health impacts add on top of other types of toxic exposure in their neighborhoods, contributing to cumulative health impacts and risks.

EPA has underestimated the health threats to which people near these facilities are exposed for all of the reasons described below, including:

(1) EPA underestimates health threats to children and from early-life exposure, including by ignoring increased risk in childhood and from prenatal exposure;

(2) EPA underestimates health threats to communities exposed to multiple sources by refusing to add factors to account for the increased risks caused by such exposure;

(3) EPA underestimates the cancer, chronic non-cancer, and acute health risks by using modeling assumptions that ignore real-world exposures, and refusing to aggregate cumulative risks.

In view of these substantial health threats, it is unlawful, arbitrary and capricious for EPA *to do nothing* to reduce any of these emissions or resulting health threats. EPA may not lawfully or rationally find health risks to be "acceptable" under § 7412(f)(2) when the record shows the opposite. HCl facilities cause presumptively *unacceptable* cancer risks. HCl sources also cause a high chronic non-cancer risk, and significant acute risks that EPA has attempted to "refine" away, without evidence that its modeling is accurate. Yet EPA does not even discuss these high risks in its acceptability determination.

EPA proposes no changes at all to reduce the health risks or the environmental injustice of this disproportionate exposure or to assure the requisite "ample margin of safety to protect public health," 42 U.S.C. § 7412(f)(2). EPA's proposal not to strengthen the standards at all pursuant to § 7412(f)(2) is also unlawful and arbitrary, because it is incomplete and based on analyses that underestimate and ignore the health risks from the toxic pollution that HCl facilities emit into communities across America, as discussed later in these comments.

The risk assessment and proposed determination are also unlawful and arbitrary because EPA has presented these numbers in the abstract – making it difficult for communities to understand the risk assessment and for the public to understand what the risks EPA has found actually mean for people's lives. For example, EPA provides only the results of its facility-wide risk assessment and acute risk modeling and refined assessment. It does not provide the emission totals it used, or the methods or data it used to calculate the facility-wide risk numbers, it just says these emissions exist. EPA provides charts and maps that belie its acute risk numbers – and fails

to explain how it moves from acute risk values above 30 and even 40 at some facilities, to a supposedly "refined" value below 1 at all facilities.

These omissions and fundamental failures to provide a reasoned explanation based on the record prejudice the affected public and make it impossible to comment meaningfully on EPA's risk assessment and proposal. EPA's proposal is therefore at odds with the public notice-and-comment requirements of the Clean Air Act, the 1994 Environmental Justice Executive Order, and EPA's own commitment in Plan EJ 2014 to provide greater community transparency and public participation in rulemakings.[9] In 2016, EPA reiterated its promise to ensure greater community transparency and meaningful public participation by extending its commitment to include building its capacity to promote action on environmental justice concerns.[10] EPA has since continued to restate its objective of "demonstrating tangible results in minority, low-income, tribal and indigenous communities," even though the current rulemaking does not advance this goal.[11]

As an additional serious problem, in this industry-specific rulemaking, EPA's Office of Air Quality Planning and Standards ("OAQPS") is seeking comment on and questioning use of the 2016 Integrated Risk Information System ("IRIS") value for the potent carcinogen ethylene oxide "for regulatory purposes." 84 Fed. Reg. at 1584. IRIS created a cancer risk assessment and values to protect public health in 2016, after a scientifically sound, multi-step, external peer-reviewed process.[12] EPA has no lawful or rational basis for ignoring that cancer risk value. Section 7412(f)(2) requires EPA to use the best available science to assess health risks, not whatever science EPA chooses. EPA has a clear protocol it uses to assess health risks, and the IRIS value is the default for EPA to use. The 2016 IRIS value is a well-supported, reasoned scientific determination, based on a substantial scientific record, after thorough vetting and in a robust, methodical and systematic review. It appears that EPA is questioning that final risk value here simply because industry groups such as the American Chemistry Council are trying to persuade IRIS to revisit it. EPA may not grant their request in this rulemaking, and may not lawfully or rationally ignore or shelve the 2016 IRIS value when that is the best available science on ethylene oxide.

Separately, the statute also requires in this rulemaking that EPA "shall review and revise, as necessary (taking into account developments in practices, processes, and pollution control technologies), emission standards promulgated under this section no less often than every 8 years." 42 U.S.C. § 7412(d)(6). Avoiding this obligation and refusing to complete the directive from Congress, as EPA proposes to do here by refusing to demonstrate that it has completed a

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[9] 42 U.S.C. § 7607(d); Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, Exec., Exec. Order No. 12898, 3 C.F.R. § 859 (1995), *reprinted as amended in* 42 U.S.C. § 4321 (1998); EPA, *Plan EJ 2014*, https://www.epa.gov/environmentaljustice/plan-ej-2014.

[10] EPA, *EJ 2020 Action Agenda*, https://www.epa.gov/sites/production/files/2016-05/documents/052216_ej_2020_strategic_plan_final_0.pdf.

[11] *See* EPA, *Environmental Justice FY2017 Progress Report* at 5, https://www.epa.gov/sites/production/files/2018-04/documents/usepa_fy17_environmental_justice_progress_report.pdf.

[12] EPA, IRIS, Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Dec. 2016), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf, and Executive Summary, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1025_summary.pdf.

technology review, and assessed and accounted for developments, would be unlawful and arbitrary.

As further discussed below, Commenters also oppose the following unlawful and arbitrary regulatory changes that EPA proposes or on which it is taking comment:

(1) EPA may not create an unlawful exemption or extension for compliance reporting as it proposes to do for web outages or so-called "force majeure events," as this violates the requirement for standards to be continuous and would allow unreported exceedances to go unchecked, indefinitely.

(2) EPA may not keep the exemption in the standards for maintenance-period exceedances, or rubberstamp the definition of "maintenance vent" that Dow Chemical has requested from the agency, so that the industry can evade the numerical emission limits during malfunctions. This would be another variation of the unlawful exemption or weakening of standards during malfunctions, so that they are not continuous and do not apply at all times as the Act requires, to meet § 7412(d)(2)-(3), and (f)(2).

Commenters support the following improvements that EPA is proposing to make pursuant to § 7412(d), as these are required to satisfy the Act and its ultimate objective to protect public health, including: (1) removing the existing standards' unlawful exemption for excess emissions during startup, shutdown, and malfunction ("SSM") periods, as required by the Act and binding legal precedent; and (2) requiring electronic reporting to assure and account for compliance.

Based on all of the evidence before EPA and to comply with the Clean Air Act, as discussed in these comments, Commenters to urge EPA to set stronger standards that will finally bring the protection that all communities deserve from toxic air pollution from HCl facilities.

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DETAILED COMMENTS

I. COMMUNITIES EXPOSED TO HCl PRODUCTION AND FACILITY EMISSIONS NEED STRONGER HEALTH PROTECTION.

EPA has identified 19 communities currently exposed to toxic air pollution from the facilities regulated by the HCl standards, in 11 states. The facilities EPA found that have the highest calculated cancer or chronic non-cancer risks are:

- Cabot Corp. in Tuscola, IL
- BASF and Rubicon in Geismar, LA (Ascension Parish)

- Honeywell in Baton Rouge, LA
- Blue Cube in Plaquemine, LA (Iberville Parish)
- Hexion in Norco, LA (St. Charles Parish)
- Dow Chemical in Midland, MI
- Polymer Additives in Bridgeport, NJ
- Momentive Performance Materials in Waterford, NY
- PPG in Barberton, OH
- Olin in Clute, TX
- Dupont in Washington, WV.

See HCl RRA App. 10 (Detailed Risk Modeling Results for all 19 facilities). Many of these HCl facilities include other sources EPA regulates and for which it is required to reduce and prevent any unacceptable health risks, such as the Miscellaneous Organic Chemical Manufacturing (MON), and Synthetic Organic Chemical Manufacturing (HON) source categories.[13]

Some HCl facilities are located in and releasing pollution into high cancer-risk areas identified by EPA's most-recent 2014 National Air Toxics Assessment, released in 2018.[14] A recent news article highlighted the particularly high risks in some of these communities, as shown in the accompanying chart.[15]

The Office of Inspector General has issued notice of a project to investigate "whether the EPA's residual RTR process has sufficiently identified and addressed any elevated cancer risks from air toxics emitted by facilities."[16]

HCl sources and facilities are releasing the following toxic air pollutants identified by EPA.

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[13] *See* https://echo.epa.gov/facilities/facility-search/results for subpart FFFF (MON) (list attached, showing, *e.g.*, that HCl facilities BASF and Rubicon in Geismar, Honeywell in Baton Rouge, Dow Chemical in Midland, MI, and Dupont in Washington WV, Momentive in Waterford, NY, Polymer Additives in Bridgeport, NJ, and Hexion/Momentive in Norco also include MON sources or miscellaneous organic chemical manufacturing sources); https://echo.epa.gov/facilities/facility-search/results for subpart G (HON or synthetic organic chemical manufacturing) (list attached, showing, *e.g.*, that HCl facilities BASF and Rubicon in Geismar, Honeywell in Baton Rouge, Dow Chemical in Midland, MI, and Dupont in Washington WV, Blue Cube in Plaquemine, Polymer Additives in Bridgeport, NJ, Momentive in Waterford, NY, and Hexion/Momentive in Norco, also include HON sources).

[14] EPA, 2014 National Air Toxics Assessment (last updated Sept. 17, 2018), https://www.epa.gov/national-air-toxics-assessment/2014-national-air-toxics-assessment.

[15] Sharon Lerner, "A Tale of Two Toxic Cities," *The Intercept* (Feb. 24, 2019), https://theintercept.com/2019/02/24/epa-response-air-pollution-crisis-toxic-racial-divide/.

[16] EPA Ofc. of Inspector Gen., Project Notification: EPA Actions to Address Air Toxics Emissions Through Its Residual Risk and Technology Review Program, Project No. OA&E-FY19-0091 (Dec. 17, 2018), https://www.epa.gov/sites/production/files/2018-12/documents/_epaoig_notificationmemo_12-17-18_airtoxics.pdf.

Hydrogen chloride (HCl) or hydrochloric acid is an acid gas that is irritating and corrosive to any tissue it contacts. Short-term exposure to low levels can cause throat irritation. Long-term exposure to low levels can cause respiratory problems, eye and skin irritation, and discoloration of the teeth. Exposure to higher levels can result in rapid breathing, narrowing of the bronchioles, blue coloring of the skin, severe burns of the eyes and skin, accumulation of fluid in the lungs, and even death. Some people may develop reactive airways dysfunction syndrome (RADS), a type of asthma caused by some irritating or corrosive substances. Children may be more vulnerable than adults to corrosive agents, such as HCl, because of their relatively narrower airways, relatively greater exposure due to greater breathing volume per pound of body weight and relatively longer potential exposure durations. [17]

Chlorine is a highly corrosive skin, eye, and respiratory irritant and is known to cause a number of serious health effects including wheezing, burning pain and blisters, chest tightness, and shortness of breath.[18] Other acute neurological effects include nausea, and blurred vision. Chronic exposure can cause severe health effects like fluid in the lungs. Similar to HCl, children may be more susceptible to the effects of chlorine due to their narrower airways.[19] An additional vulnerability for children is due to the physical property of chlorine gas being heavier than air; children are more vulnerable because of their shorter stature, which results in higher exposure if chlorine is present in low-lying areas.[20]

Ethylene oxide (EtO) is a flammable, colorless gas and is a known carcinogen and neurotoxicant that can also cause acute health impacts to the eyes, skin, nose, throat and lungs.[21] EPA recently identified this chemical "as a potential concern in several areas across the country" as part of the most recent National Air Toxics Assessment ("NATA").[22] EPA has found that: "[t]he DNA-damaging properties of [ethylene oxide] have been studied since the 1940s," and that it is "carcinogenic to humans" through inhalation.[23] Other scientists and health experts have independently confirmed this finding, including the National Toxicology Program, the International Agency for Research on Cancer, and the Occupational Safety and Health

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[17] Agency for Toxic Substances and Disease Registry ("ATSDR"), ToxFAQs for Hydrogen Chloride, http://www.atsdr.cdc.gov/toxfaqs/TF.asp?id=759&tid=147; Cal. Office of Envtl. Health Hazard Assessment, Hydrogen Chloride, https://oehha.ca.gov/chemicals/hydrogen-chloride.

[18] ATSDR, Medical Management Guidelines for Chlorine, https://www.atsdr.cdc.gov/mmg/mmg.asp?id=198&tid=36.

[19] ATSDR, Toxicological Profile for Chlorine, Chapter 2 – Relevance to Public Health, https://www.atsdr.cdc.gov/toxprofiles/tp172-c2.pdf.

[20] *Id.* at 14.

[21] EPA, IRIS, Ethylene Oxide (last updated July 28, 2017), https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1025.

[22] EPA, Background Information on Ethylene Oxide (last updated Feb. 27, 20192018), https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/background-information-ethylene-oxide; EPA 2014 NATA: Assessment Results, https://www.epa.gov/national-air-toxics-assessment/2014-nata-assessment-results.

[23] EPA, IRIS, Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide at 2, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1025_summary.pdf.

Administration.[24] The American Chemistry Council has published a manual on this chemical which highlights acute health and safety threats and the need to take steps to avoid them.[25] In 2016, EPA scientists in the IRIS program updated the health reference value for cancer risks from ethylene oxide recognizing that it is far more carcinogenic than previously understood.[26] EPA has stated its commitment to "review Clean Air Act regulations for facilities that emit ethylene oxide to ensure that they protect the public."[27] Yet, as discussed below, EPA fails to follow through to assure protection from this or other chemicals emitted by HCl facilities, and attempts to defer action needed to reduce exposure to this toxic pollution.

Trichloroethylene (TCE) is a known carcinogen and causes developmental and immunological impacts. Both epidemiological and toxicological studies have found adverse effects when exposed to TCE and there is especial concern for *in utero* exposure as TCE has been associated with congenital heart defects.[28] Other studies have linked TCE exposure to adverse effects in the nervous system leading to the development of Parkinson's disease.[29] Acute exposure to TCE can cause effects to the nervous system, including headaches, drowsiness, and trouble with eyesight and balance. Other observed effects include harm to the liver, respiratory system, kidneys, and heart.[30] TCE is commonly used as a degreasing agent; EPA has considered a ban of certain uses of TCE and is currently assessing other risk management options.[31]

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In this rulemaking process, EPA held a public hearing on the HCl proposed rule, after eighteen environmental and community nonprofit organizations, a member of Congress (U.S. Rep.

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[24] National Toxicology Program, Report on Carcinogens, Fourteenth Addition, Ethylene Oxide (2016), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/ethyleneoxide.pdf; International Agency for Research on Cancer, IARC Monographs 100F Ethylene Oxide (2012), https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100F-28.pdf; Occupational Safety and Health Administration, OSHA Fact Sheet Ethylene Oxide (2002), https://www.osha.gov/OshDoc/data_General_Facts/ethylene-oxide-factsheet.pdf.

[25] ACC, Ethylene Oxide Panel Ethylene Oxide Safety Task Group, EO Product Stewardship Manual (3d Ed.), https://www.americanchemistry.com/EO-Product-Stewardship-Manual-3rd-edition/; *see also* Ethylene Oxide and Derivatives Producers Ass'n, *Guidelines for the distribution of Ethylene Oxide* (Fourth Revision, 2013), https://www.petrochemistry.eu/wp-content/uploads/2018/01/Guidelines_EO_2013_UK_v6-final.pdf.

[26] EPA IRIS, Ethylene Oxide, https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf.

[27] EPA, Fact Sheet: EPA Taking Steps to Address Emissions of Ethylene Oxide (2018), https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/fact-sheet-epa-taking-steps-address-emissions-ethylene-oxide

[28] EPA, IRIS, Trichloroethylene (last updated July 28, 2017), https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=199.

[29] The National Academies, *Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues* (2006), https://www.nap.edu/resource/11707/trichloroethylene_brief_final.pdf.

[30] *Id.*

[31] EPA, Risk Management for Trichloroethylene (TCE) (last updated Dec. 14, 2017), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-trichloroethylene-tce.

Daniel Lipinski, IL), and DuPage County requested this.[32] EPA scheduled this in D.C., requiring people to travel to Washington, D.C. if they wished to participate. In that public hearing, EPA heard from people around the country – including from Louisiana, West Virginia, and Illinois, as well as Delaware, who are concerned both about this specific proposal and about EPA's unusual attempt in this proposed rule to undermine or ignore the 2016 IRIS cancer risk value more broadly.

Since EPA released the 2014 NATA in August 2018, communities have learned that they have been exposed for years to unacceptably high emissions of ethylene oxide and other carcinogens. This rulemaking is the first EPA is undertaking where it has a responsibility to start reducing this harm. Because that value is relevant to all other sources that emit ethylene oxide, such as other chemical manufacturing sources and sterilizers, EPA should listen to the concerns of communities, scientists, advocates, members of Congress, and state air agencies who have called on EPA to recognize the need to continue using the 2016 IRIS value and to strengthen health protection in doing so.[33]

Commenters respectfully request that EPA consider the people exposed to HCl facilities' emissions and affected by its proposed decision not to strengthen standards at all, as EPA has found extremely high cancer and other health risks. Commenters urge EPA to exercise its full legal authority to finally end all unacceptable risk for exposed communities, and set the "ample margin of safety to protect public health" that the Clean Air Act requires, instead of attempting to avoid the science and high health threats shown in the record.

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[32] Comment by Alliance for the Great Lakes et al., EPA-HQ-OAR-2018-0417-0042 (Feb. (Feb. 17, 2019), https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0417-0042; Comment by Rep. Daniel Lipinski et al.,EPA-HQ-OAR-2018-0417-0048; EPA-HQ-OAR-2018-0417-0048 (Feb. 8, 2019), https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0417-0048; Comment by DuPage County Board and DuPage County Health Dep't, EPA-HQ-OAR-2018-0417-0121 (March 21, 2019), https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0417-01210021.

[33] *See, e.g.*, Comment by National Ass'n of Clean Air Agencies (NACAA), EPA-HQ-OAR-2018-0417-0122) (Mar. 28, 2019), https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0417-0122; Comment by Rep. Lipinski et al., EPA-HQ-OAR-2018-0417-0048 (Feb. 8, 2019), https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0417-0048. U.S. Rep. Daniel W. Lipinski also testified at EPA's public hearing on March 27, 2019. *See also* Letter to Adm'r Wheeler from Sens. Duckworth & Durbin & IL Congressional Delegation (Jan. 20, 2019) ("Since EPA updated the carcinogenic risk value of EtO, the American Chemistry Council (ACC) has lobbied EPA to withdraw its assessment. The chemical industry appears to be following the playbook established by the fossil fuel industry when it sought to undermine climate change science and by tobacco companies when they attempted to cover up the danger of their products"); Letter to Adm'r Wheeler from Senators and IL Congressional Delegation at 2 (Feb. 13, 2019) (calling on EPA to use the 2016 IRIS assessment "for determining inhalation risk values. Doing otherwise would be a departure and contradiction to the Agency's own longstanding policy").

II. EPA'S PROPOSED DETERMINATION THAT HCl FACILITIES' HEALTH RISKS ARE ACCEPTABLE IS UNLAWFUL AND ARBITRARY.

The purpose of the Clean Air Act is to protect public health by preventing air pollution.[34] The statutory test for the health risk rulemaking under § 7412(f)(2) is two-fold: (1) EPA must prevent all unacceptable health risks; and (2) EPA must assure an "ample margin of safety to protect public health" and "prevent … an adverse environmental effect."[35]

Under section 112(f), EPA must first assess the health risk created by toxic air emissions from a source category which remains once an existing MACT standard is in place and determine whether this risk is "acceptable" or not.[36] If the health risk is unacceptable, EPA must set a standard to prevent unacceptable risk. Then, at step two, EPA is required to consider whether further health risk and emission reductions are needed to provide an additional, "ample margin of safety to protect public health," in view of scientific uncertainty regarding its own risk assessment.[37] This provision requires EPA both to prevent unacceptable risk and provide a buffer or cushion, between the line of acceptability EPA draws, and the emission limit – to ensure that in the event EPA's acceptability line is incorrect (*e.g.,* due to the many uncertainties shown in EPA's risk assessment), facilities will not be allowed to emit right up to the line of what is unacceptable, and must instead emit at levels lower than that. The difference between the two is the "ample margin of safety" required by the Act.

As the D.C. Circuit has explained, the "aspirational goal" of § 7412(f)(2) includes reducing lifetime cancer risk to the most-exposed person to be one-in-one million or lower.[38] EPA has recognized that this provision requires the agency to "protect[] the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million" and "limit[] to no higher than approximately 1 in 10 thousand [*i.e.*, 100-in-1 million] the estimated risk that a person living near a plant would have if he or she were exposed to the maximum pollutant concentrations for 70 years."[39]

A. EPA should find that current residual risk from HCl production sources and facilities is unacceptable and requires action.

EPA proposes that the health risks it has found are acceptable, because it finds that certain HCl-source risks are low and uses those to attempt to justify its acceptability determination. 84 Fed. Reg. at 1583. Instead, to satisfy the Act and requisite principles of reasoned decision-making, EPA should find the health risks from HCl facilities are unacceptable for any one, and for all, of the following reasons in the record:

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[34] 42 U.S.C. § 7401(b)(1) ("purposes" include "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population"); *id.* § 7401(c) ("primary goal … is … pollution prevention"); *see also id.* § 7401(a)(2).
[35] *Id.* § 7412(f)(2)(A).
[36] *NRDC v. EPA*, 824 F.2d 1146, 1164 (D.C. Cir. 1987) (vinyl chloride decision) (en banc).
[37] *Id.* at 1165; 42 U.S.C. § 7412(f)(2).
[38] *NRDC v. EPA*, 529 F.3d 1077, 1082 (D.C. Cir. 2008) (interpreting 42 U.S.C. § 7412(f)(2)).
[39] 54 Fed. Reg. 38,044, 38,044-45 (Sept. 14, 1989) ("Benzene Rule").

- The HCl facility-wide cancer risk EPA has found is 600-in-1 million, or *six times* the level it deems presumptively *unacceptable* (100-in-1 million);

- the HCl facility-wide chronic non-cancer risk is 6 – *six times* the HQ of 1 where harm occurs;

- the HCl source category-specific chronic non-cancer risk is at least 2, *two times* the HQ of 1;

- there is acknowledged acute risk on top of all of those health threats that could be as high as an HQ of 42, and appears to be well above 1; *and*

- all of its risk assessment values are underestimates, because they have gaps that ignore components of real-world health risks, as discussed later in these comments.

First, in view of these risks and EPA's inadequate risk assessment, *see* Part IV, *below*, EPA has failed to satisfy § 7412(f)(2) of the Act. EPA cannot ignore unacceptable risk under § 7412(f)(2), and may not use cost or any other justification for doing so.

As a matter of law and EPA's own implementation of § 7412(f)(2), EPA's proposal violates the Act. EPA has long had a presumption that cancer risk above 100-in-1 million is unacceptable. *See* Part II.C, below. The D.C. Circuit has found that the Act incorporates that presumption, such that EPA must deem such cancer risk unacceptable. *See NRDC*, 529 F.3d at 1082 (finding that "the Benzene standard established a maximum excess risk of 100-in-one million, while adopting the one-in-one million standard as an aspirational goal," and that "[t]his standard [was] incorporated into the amended version of the Clean Air Act").

Yet EPA has failed to find that risk from the HCl facilities is unacceptable, even when its own assessment demonstrates presumptively unacceptable cancer risk. Instead, it has made its determination of acceptability by *ignoring* the facility-wide risk. Based on the record the agency has created and the evidence before it, EPA can have no lawful basis for refusing to recognize and find that the cancer risk from HCl facilities *is unacceptable*. It is six times EPA's own presumptive benchmark.

As the D.C. Circuit held in interpreting the same language in the prior version of § 7412:

> We find that the congressional mandate to provide "an ample margin of safety" "to protect the public health" requires the Administrator to make an initial determination of what is "safe." This determination must be based exclusively upon the Administrator's determination of the risk to health at a particular emission level.

NRDC, 824 F.2d at 1164.[40] Finding unsafe risk, EPA must say so. EPA may not call these facilities' risk acceptable when it knows it is not. At least, EPA must recognize that the level of

[40] The court further elaborated that: "the Administrator's decision must be based upon an expert judgment with regard to the level of emission that will result in an 'acceptable' risk to health. . . . In this regard, the

emissions from HCl facilities is currently unsafe, and requires regulatory reduction. Yet, it has failed to do so. Further, as cancer risk of 1-in-1 million is the "aspirational goal" of the statute, EPA must also describe what it will do to reduce emissions and risks, yet it does neither. This contravenes the Act.

Second, EPA's proposed risk acceptability determination is also unlawful and arbitrary because it is inconsistent with EPA's longstanding presumption of unacceptability, as stated in the Benzene Rule. 54 Fed. Reg. at 38,044-45. Yet EPA neither acknowledges a change in course, nor provides any reasoned explanation for this departure from prior practice. This is the definition of arbitrary and capricious. *See, e.g.*, 42 U.S.C. § 7607(d)(9); *FCC v. Fox Television*, 556 U.S. 502, 515 (2009); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). EPA has failed to "protect[] the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million" and "limit[] to no higher than approximately 1 in 10 thousand [*i.e.*, 100-in-1 million] the estimated risk that a person living near a plant would have if he or she were exposed to the maximum pollutant concentrations for 70 years."[41]

Third, EPA may not simply look only at some risks, call those low and use that partial conclusion to justify its acceptability determination, 84 Fed. Reg. at 1583. EPA may not cherry-pick the health risk information it considers from its Residual Risk Assessment; it must make a determination based on all of the available evidence, including all of the substantial health risks it has actually found. In view of the full record, EPA has failed to provide any reasoned explanation for why the extremely high cancer and chronic non-cancer risks from HCl production facilities could possibly be considered "acceptable." Even if they could be considered acceptable in a vacuum, that is not reality. People are not just breathing HCl sources' pollution, which is bad enough on its own. The reality is communities are exposed to these facilities' emissions together, as a whole, cumulatively, and so EPA must also evaluate the acceptability of the risk to the "most exposed" individual as they experience it – from the whole facility.

In particular, EPA does not even discuss the HCl-source category specific TOSHI, which is higher than 1. EPA also *does not even discuss the extremely high facility-wide health risks* – Maximum Individual Risk ("MIR") of 600-in-1 million, and TOSHI of 6 – in making its acceptability determination, much less give any explanation for how these data could support its determination. 84 Fed. Reg. at 1583. Although EPA presents those high-risk findings in the notice of proposed rulemaking and the risk assessment, it *ignores* and does not even address these where it most matters: in its proposed acceptability determination.

EPA has given and can give no reasoned justification at all for ignoring these health risks in deciding whether residual risk is acceptable or not. EPA has recognized the need to assess the TOSHI – the total organ or organ system-specific health index, for chronic non-cancer risk. It has also recognized the need to assess facility-wide risk to "consider[] exposure to HAP emissions from the source category *and* facility." *Id.* at 1574 (emphasis added). To follow current science

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Administrator must determine what inferences should be drawn from available scientific data and decide what risks are acceptable in the world in which we live." *NRDC*, 824 F.2d at 1164-65 (citing *Envtl. Def. Fund v. EPA*, 598 F.2d 62, 83-84 (D.C. Cir. 1978)).

[41] 54 Fed. Reg. 38,044, 38,044-45 (Sept. 14, 1989) ("Benzene Rule").

and attempt to account for the maximum health risk which "the individual most exposed" faces, as the Act requires, EPA must assess these health risks. 42 U.S.C. § 7412(f)(2). Yet EPA tries to ignore these critical data points at the time when they should most count – at the acceptability determination stage. EPA can have no lawful or rational basis to do so.

In addition, EPA also deceptively and incorrectly suggests that the chronic TOSHI is less than 1, when its own data shows it is *twice that*, based on allowable emissions. 84 Fed. Reg. at 1582 tbl.2; HCl RRA at 38-39. EPA says, "a TOSHI less than 1 indicates that the combined HAP affecting a particular target organ are not likely to cause adverse chronic noncancer health effects." 84 Fed. Reg. at 1583. But EPA found a TOSHI of *2* based on allowable emissions. It does not discuss this number at all in the unacceptability determination or explain why it is ignoring it. EPA has recognized that it is important and "inherently reasonable" to use the "MACT-allowable level" in the risk assessment because "risk reflects the maximum level facilities could emit and still comply." 84 Fed. Reg. at 1576. EPA can have no lawful or rational basis to ignore and not even discuss the fact that chronic non-cancer risk for HCl sources, *alone*, is *above* a TOSHI of 1.

Fourth, it is arbitrary for EPA to find risk acceptable in view of additional evidence of uncertainty in the record. EPA should also find the current health risks to be *unacceptable* because of the omissions, underestimates, and uncertainties its own risk assessment contains. EPA has failed to show, based on evidence in the record, that the risks are not significantly higher than the values it has presented. EPA has failed to justify its acceptability determination when such major gaps are present. As discussed in further detail below:

- EPA has failed to follow the most current science to come up with each health risk value it uses, and each is likely to be an underestimate, for reasons discussed above.

- For example, EPA has significantly underestimated the cancer risk from inhalation. EPA has not shown that if it used the current science, and corrected its underestimation of the risk from early exposure, it would not find the inhalation-based cancer risk facility-wide exceeds EPA's presumptive benchmark by even more than EPA initially finds.

- EPA has also not completed a multipathway risk assessment for any pollutant, including from collocated facilities, and thus has underestimated the cancer risk, at least, from multipathway exposure for people near HCl facilities. EPA has not shown that if it fully assesses multipathway cancer risk and adds that to the inhalation risk, that the MIR would not exceed EPA's presumptive limit by even more than EPA initially finds.

- EPA should recognize that the combination of cancer, chronic non-cancer and acute risks, together, create unacceptable risk, particularly where EPA has underestimated all other kinds of risk as well, as described above.

- EPA should recognize that the cumulative impacts and multiple source exposure from various sources outside of the facility-wide boundaries make the risk to the people most exposed to these facilities' pollution even more unacceptable.

- EPA has found facility-wide cancer risks based on so-called "actual" emissions, and that these sources contribute significant percentages to that risk. EPA did not evaluate facility-wide risk based on "allowable" emissions, and if it did, this would likely increase the risks found even more.

- EPA also should decide that it is unjust and inconsistent with the Act's health-protection purpose to allow the health risks caused by these sources to fall disproportionately on communities of color and lower income communities who are least equipped to deal with the resulting health effects without doing *anything* to reduce those risks. Because of that disparity, EPA should recognize that the risks found are unacceptable and set stronger national standards for all exposed Americans.

EPA should not ignore the reality communities near HCl facilities face daily, and instead should find that their health risks are currently "unacceptable," and set residual risk standards to reduce those risks. No one should have to face significantly higher cancer, chronic non-cancer risk to the kidneys, liver, and respiratory, immunological, developmental, neurological, and reproductive systems, and acute risks just because they live near an HCl facility, particularly when they are also facing extra health threats from other sources simultaneously as well.

Finally, EPA may not lawfully or rationally refuse to consider or use the facility-wide risks it has found, at all, in making its acceptability determination. These are part of the health risks affecting the "individual most exposed" to HCl sources' emissions. 42 U.S.C. § 7412(f)(2). Thus, ignoring them would lead EPA to fail to assess the "lifetime excess cancer risks" and other health risks for this individual, as the Act requires.

EPA has recognized that it is necessary to consider facility-wide risks here, and that is why it performed the facility-wide risk assessment. 84 Fed. Reg. at 1574, 1584. However, EPA has attempted to limit its consideration of facility-wide risk to the ample margin of safety stage only, without any lawful or rational justification for doing so. *Id*. at 1584. There is no language in the statute that allows EPA to consider some health risks only at the ample margin stage. Rather, at that stage, the statute adds *other factors* EPA may consider (beyond health).

The Act requires EPA to perform a residual risk rulemaking for each "source category," but requires EPA to regulate based on the "*lifetime excess cancer risks to the individual most exposed* to emissions from a source in the category." 42 U.S.C. § 7412(f)(2) (emphasis added). EPA has repeatedly interpreted this as requiring consideration of health risks to that person who is exposed; not merely to assess emissions or risks from a given source in a category. For example, in the 1999 Residual Risk Report to Congress, EPA stated that its policy was to implement the Commission on Risk Assessment and Risk Management recommendations from 1997 to "examine and choose risk reduction options in light of total facility risks and public health context." *See, e.g.*, EPA, *Residual Risk Report to Congress* at 22, 129, EPA-453/R-99-001 (Mar. 1999), https://www.epa.gov/sites/production/files/2013-08/documents/risk_rep.pdf.

To properly perform a § 7412(f)(2) assessment, therefore, EPA must actually evaluate the full scope of cumulative health risks to which the most-exposed individual is exposed. The Act requires EPA to focus on the person "most exposed" and protect public health. EPA must satisfy

the Act's directive "to provide an ample margin of safety to protect public health in accordance with this section . . ." 42 U.S.C. § 7412(f)(2). This provision does not say to protect public health *only from the source category*. This language governs the risk assessment and the acceptability determination as well as the ample margin determination, as EPA has explained in the preamble to the proposed rule.

Because a holistic risk assessment is needed to satisfy this provision, EPA has performed a facility-wide risk assessment for many source categories, for over 10 years. EPA would not be performing that assessment if it did not produce data EPA believed and recognized that it must consider in deciding what regulatory action to take. Since at least 2005, EPA has recognized the need to assess "facility-wide risks" and consider them under § 7412(f)(2). 70 Fed. Reg. 19,992, 19,998 (Apr. 15, 2005).[42] There EPA stated that:

> EPA disagrees that section 112(f) precludes EPA from considering emissions other than those from the source category or subcategory entirely. EPA must still determine whether additional reductions should be required to protect public health with "an ample margin of safety." EPA believes one of the "other relevant factors" that may be considered in this second step is co-location of other emission sources that augment the identified risks from the source category.

70 Fed. Reg. at 19,998. In the Coke Ovens Rule, EPA attempted to limit this to the ample margin of safety stage, citing the Benzene Rule. *Id.* However, the language the Coke Ovens Rule cites from the Benzene Rule focuses on "background levels" and "all exposures to benzene;" it did not justify ignoring multiple sources where such information is available.

In the Benzene Rule, EPA found that multiple source information would be too difficult to use or would not likely change the risk assessment outcome, not that it could not be required and necessary to consider where those circumstances were not present. Overall, EPA recognized that in determining the acceptability of risk, EPA "intends to weigh [the presumption for MIR] with a series of other health measures and factors. . . . includ[ing] . . . **effects due to co-location of facilities.**" 54 Fed. Reg. at 38,045 (emphasis added). Therefore, EPA promised to assess the acceptability of health risks "'in the world in which we live,'" and "on the basis of a broad set of health risk measures and information." *Id.* at 38,046.

And, although EPA did not adopt a facility-wide risk determination in the Benzene Rule, there it was focusing on only one chemical, and made a determination that multiple sources would not likely change the analysis it performed for emissions of that chemical. EPA's decision in that rule that it was not practical and would not make a difference there to look beyond individual sources was not an interpretation of the statute. Rather, in applying § 7412(f)(2) in that rule, EPA stated that it "agrees that exposures to background concentrations **and multiple sources of a pollutant may be considered to the extent that it is practical and reasonable to do so.**" 54 Fed. Reg. at 38,059 (emphasis added). EPA also explained in the Benzene Rule that "EPA agrees that multiple exposures to chemicals are **important to understand and consider** in the EPA's

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[42] All § 7412(f)(2) rules since then have also assessed and considered facility-wide risks. EPA, Risk and Technology Review (last updated April 18, 2019), https://www3.epa.gov/airtoxics/rrisk/rtrpg.html.

overall implementation of its public health mandates." *Id.* (emphasis added). Although EPA stated in 1989 that it "disagrees that these exposures should be routinely evaluated and considered in *selecting standards* under section 112," because this would be "difficult and possibly impractical"; it did not say in the Benzene Rule that *if EPA had surmounted the difficulty of gathering such information*, that such information about multiple source exposures and risks could be *ignored* in deciding whether health risk is acceptable or not.

Here, EPA has found that facility-wide information is not difficult or impractical to create; it has reached conclusions regarding facility-wide risk values. And, because these numbers are extremely high, so high that they are above the presumptive unacceptability benchmark, using them would change the outcome of the determination. For people exposed to multiple sources at the same facility, collocation is the world "'in which [they] live,'" and thus cannot be ignored. *Id*. at 38,046. Therefore, the Benzene Rule-specific reasoning also shows EPA must consider facility-wide risks here in determining acceptability, and does not justify ignoring such risks.

That EPA has previously refused to assess facility-wide risk in some rules and has considered facility-wide risk only at the ample margin of safety stage in some rules does not mean that it may ignore these risks at the acceptability stage for *this rule*. An unlawful or arbitrary past practice cannot justify violations of the Act or irrational decisionmaking in this rulemaking. The fact is that EPA has the information needed to consider the facility-wide risks and determine whether they are unacceptable.

Importantly, to follow current science and comply with the Act, EPA has repeatedly and gradually strengthened its risk assessment approach over time (even though it still remains behind the best available science). In doing so, EPA has recognized that it may not freeze its risk assessment approach as of 1989. Instead, as EPA stated in this risk assessment, it recognizes that it must use "the best available science," HCl RRA at 24, and it has updated its risk assessment methods in certain ways over time to incorporate current science, such as in response to Science Advisory Board ("SAB") recommendations in 2010. 84 Fed. Reg. at 1574-75.

EPA contemplated and made clear even in the Benzene Rule that it must consider "the science policy assumptions and uncertainties associated with the risk measures, and the weight of evidence that a pollutant is harmful to health" as "important factors to be considered." 54 Fed. Reg. at 38,046. EPA stated that "the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information." *Id.* As EPA similarly acknowledged, the D.C. Circuit has directed EPA to make the "safe" or "acceptable risk" determination based on "available scientific data" and by "decid[ing] what risks are acceptable in the world in which we live." *Id.* at 38,049 (citing *NRDC v. EPA*, 529 F.2d at 1165). Refusing to use current science, which makes it possible to assess and consider facility-wide risk, would mean not using available scientific data, or basing a determination on *today's* world.

Finally and importantly, as EPA acknowledges in the ample margin of safety section, EPA well knows the chemicals and sources that are collocated with HCl sources contribute to high cancer and chronic noncancer risks here. 84 Fed. Reg. at 1584. EPA has authority over the collocated sources that are part of regulated source categories as well, though it is trying to defer action to control their pollution. *Id.* It cites specific source categories and states that "we intend to

evaluate those facility-wide estimated emissions and risks further and may address these in a separate future action, as appropriate." 84 Fed. Reg. at 1584.

Here, those include, at least, certain chemical manufacturing and other industrial processes EPA has acknowledged. 84 Fed. Reg. at 1583; HCl RRA at 37-38. EPA would not have included those sources in the facility-wide risk assessment if they were not "HAP-emitting operations within a contiguous area and under common control," including "all other emission sources at the facility for which [EPA] ha[s] data." 84 Fed. Reg. at 1579. In response to Science Advisory Board recommendations, EPA has recognized the need to perform facility-wide risk assessments for use in source category rulemakings. *Id*. at 1575. EPA cannot therefore ignore these risks, or refuse to address them at all in determining whether cancer risk is unacceptable for the "most exposed" individual. Doing so would violate the plain text and intent of § 7412(f)(2) which requires EPA to protect the "most exposed" person from unacceptable risk – which is present here, based on EPA's own presumption and longstanding policy.

EPA has identified data showing that there are unacceptable health risks in this rulemaking, it has authority over the collocated sources at the same facility, and it has no lawful or rational justification for refusing to strengthen the emission standards covering this facility without any further delay. It must therefore, first, ensure this unacceptable risk is reduced below EPA's presumptive level (and should go further because that benchmark is too high, as discussed in Part II.C, below). EPA must then set emission standards that assure an "ample margin of safety to protect public health" from HCl sources and facilities, as discussed in Part III, below.

B. EPA's proposal properly considers and applies the 2016 IRIS cancer risk value for ethylene oxide and EPA may not lawfully ignore that value.

In this risk assessment, EPA has correctly used the 2016 IRIS value for cancer risk from ethylene oxide, to assess facility-wide risk at HCl facilities. 84 Fed. Reg. at 1584. EPA determined that the "full lifetime unit risk estimate" including age-dependent adjustment factors due to early-life exposure, is 5.0×10^{-3} or 0.005 $\mu g/m^3$, and also provided additional adult-based unit risk estimates for certain kinds of cancer incidences.[43] IRIS determined that EPA has "relatively high" confidence in the unit risk estimate, "based on strong epidemiological evidence supplemented by other lives of evidence," including "a large, high-quality epidemiology study with individual worker exposure estimates," and found that the method of linear low-exposure extrapolation used "is strongly supported," and that "[c]onfidence . . . is particularly high for the breast cancer component," based on "over 200 incident cases."[44]

However, EPA also states that it is taking comment on whether to use that value here and for other "regulatory purposes." *Id.* at 1585. EPA provides no proposed rationale of any kind for ignoring the 2016 IRIS value.

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[43] EPA, *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, Executive Summary* at 5-6 (Dec. 2016), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/1025_summary.pdf.
[44] *Id.*

EPA may not lawfully ignore that value because it represents the best available science, which EPA must use in its § 7412(f)(2) rulemakings. EPA also may not ignore it because doing so would be arbitrary and capricious as this value is scientifically robust and not using it would lead EPA to underestimate health risk for the most-exposed person. EPA has no reasoned basis on which to set aside the 2016 IRIS value.

IRIS is a separate, scientist-led office at EPA, intentionally insulated from regulatory processes to ensure a health-protective and science-based (not a political or policy preference) approach.[45] IRIS is charged with evaluating the toxicity of chemicals, using the best available scientific and health information. That is precisely what the agency did in creating the 2016 IRIS value, as the 2016 IRIS documentation shows, and as scientists' comments and testimony in the record have emphasized.[46] The 2016 IRIS value is the product of a 10-year long, peer-reviewed process, including public notice-and-comment.[47]

The Act requires EPA to consider and use the best available science regarding health risks and effects, to assess and regulate air toxics. For example, § 7412(f) requires EPA to investigate and report, among other things, on "the actual health effects with respect to persons living in the vicinity of sources," and "***any available epidemiological or other health studies***" regarding the effects of HAPs, as part of the residual risk requirements. 42 U.S.C. § 7412(f)(1)(C) (emphasis added); *id.* § 7412(f)(1) (also providing other requirements for EPA's investigation and report to Congress). It would not be possible for EPA to fulfill its statutory directives under § 7412(f)(2) to ensure that air toxics emissions standards "provide an ample margin of safety to protect public health," and to assess and prevent all unacceptable health risks, unless EPA considers the best available scientific studies in assessing such health risks. *Id.* § 7412(f)(2).

As EPA determined, and Congress, the D.C. Circuit, and EPA have affirmed through citation and reliance on that rule, § 7412(f) standards must be "based on the most current scientific knowledge," and on risk assessment guidelines and methods developed by EPA scientists and expert independent scientists. 54 Fed. Reg. at 38,062-63. In the Benzene Rule, for example, EPA explained that risk assessments and § 7412(f) rules must be based on "the most current scientific knowledge and on sound scientific judgment"; EPA stated that it had based that rule on "an evaluation of the currently available information and on the regulatory mission of EPA to protect public health." *Id*. In rules since then, EPA has continued to affirm this core directive of

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[45] EPA, Basic Information about the Integrated Risk Information System (last updated Oct. 22, 2018), https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system.

[46] *See, e.g.*, Letter from Scientists to EPA (Apr. 26, 2019) (filed by J. Sass, NRDC); Testimony of Jennifer Sass, Senior Scientist, NRDC (Mar. 27, 2019); Testimony of Michelle Mabson, Staff Scientist, Earthjustice (Mar. 27, 2019); *see also* J. Sass, NRDC, ACC/TSCA Attack on IRIS: Formaldehyde, Chloroprene, EtO (Mar. 26, 2019), https://www.nrdc.org/experts/jennifer-sass/acctsca-attack-iris-formaldehyde-chloroprene-eto.

[47] EPA, IRIS, Ethylene Oxide, History, https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1025#tab-3 (describing IRIS's work from 2006-16 on the 2016 IRIS value for inhalation carcinogenicity); *see* EPA, Notice of a Public Comment Period on the Draft IRIS Carcinogenicity Assessment for Ethylene Oxide, 78 Fed. Reg. 44,117 (July 23, 2013); *see* IRIS EtO docket, https://www.regulations.gov/docket?D=EPA-HQ-ORD-2006-0756.

§ 7412(f)(2). EPA has repeatedly recognized its legal responsibility pursuant to § 7412(f) includes "incorporating into our assessments the best available science with respect to dose-response information."[48]

Under its longstanding science policy, and as stated in the Residual Risk Assessment here, EPA has a policy of prioritizing certain scientific authorities for dose-response information according, in part, to "level of peer review received,"[49] to use "the best available science with respect to dose-response information. The recommendations are based on the following sources, in order of priority": (1) EPA IRIS values which have all gone through independent, external peer-review; (2) ATSDR values, which follow an approach similar to EPA's IRIS program; and (3) Cal. EPA values for which "[t]he process for developing these assessments is similar to that used by EPA to develop IRIS values and incorporates significant external scientific peer review." HCl RRA at 24-25 (similar to prior RRAs).

EPA's scientific method is to consult and rely on IRIS's toxicity database as the first priority source of such information, due in part to the high level of peer review and EPA's robust IRIS process. As EPA's guidelines explain: "IRIS is a critical resource for risk assessors because the database contains toxicity information that reflects a consensus among EPA program offices."[50] EPA sometimes uses other reference values that meet its longstanding scientific standards, such as those created by California Office of Environmental Health Hazard Assessment, when that satisfies "consistency" with EPA's guidelines and if there has been sufficient "peer review received." *See* HCl RRA at 24 (EPA follows a "periodization process aimed at incorporating into our assessments the best available science with respect to dose-response information").

Refusing to use the 2016 IRIS, or other health reference values that that represent the best available science, would represent a significant backward step by EPA, away from the statute and its objectives, as well as an about-face from its well-developed scientific policy and current

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[48] EPA, *Residual Risk Assessment for the Portland Cement Manufacturing Source Category in Support of the September 2017 Risk and Technology Review Proposed Rule* at 23 (July 2017), https://www.regulations.gov/document?D=EPA-HQ-OAR-2016-0442-0153 (describing the Agency's current policy and scientific methodology for this type of health risk assessment); *see also e.g.*, EPA, *Residual Risk Assessment for Pulp Mill Combustion Sources in Support of the October, 2017 Risk and Technology Review Final Rule* at 6, 18-19 (July 2017), https://www.regulations.gov/document?D=EPA-HQ-OAR-2014-0741-0266 (same).

[49] HCl RRA at 24 (citing EPA 2014a Table: updated version available at EPA, Table 1: Prioritized Chronic Dose-Response Values for Screening Risk Assessments (June 18, 2018), https://www.epa.gov/sites/production/files/2014-05/documents/table1.pdf).

[50] EPA, *Air Toxics Risk Assessment Reference Library*, Vol. 1 Tech. Res. Manual, EPA-453-K-04-001A at 3-9 (April 2004), https://www.epa.gov/sites/production/files/2013-08/documents/volume_1_reflibrary.pdf; *id.* at 12-25 ("Dose-response assessments that have achieved full intra-agency consensus are incorporated in the Integrated Risk Information System (IRIS), which is regularly updated and available on-line (www.epa.gov/iris).").

methods which are based on years of evaluation and have gone through extensive peer review by the Science Advisory Board.[51]

EPA has not justified and could not justify this departure from scientific policy without a reasoned explanation that acknowledges and explains the change with the requisite level of detail and satisfies the Act's objectives. 42 U.S.C. § 7607(d)(9); *FCC v. Fox Television*, 556 U.S. at 515; *State Farm*, 463 U.S. at 43. EPA has given no explanation whatsoever for questioning the final 2016 IRIS value, nor any basis on which it could ignore or decide not to use this value for regulatory purposes and still satisfy § 7412(f)(2). Thus, it would be arbitrary to do so.

Further, ignoring or refusing to use the 2016 IRIS value would also violate notice-and-comment without providing any lawful and rational ground for this decision, and for changing course. 42 U.S.C. § 7607(d)(3)-(7), (h). EPA must release its rationale and basis for a proposed rule, as the Act requires, or the affected public has no ability to meaningfully comment.

Moreover, EPA could not ignore or stop using the 2016 IRIS value without following the usual IRIS external peer-review process to create a new value. That process occurs in the IRIS office, has many steps to assure scientific integrity and data quality, and is led and performed by scientists, not policymakers or rule writers.[52] Until EPA completes and issues an updated value, OAQPS must use the current value. All available evidence cited by the 2016 IRIS value and available regarding EtO demonstrates that value is robust and the most accurate reflection of cancer risk caused by EtO. There is no scientific or lawful basis to ignore it.

Therefore, EPA must use the best available science in this rulemaking – which includes the 2016 IRIS value for EtO.

C. EPA's proposal relies on an outdated policy regarding health risks, where EPA presumes that cancer risk is not unacceptable until it reaches 100-in-1 million, and EPA refuses to consider any level of other kinds of health risks presumptively unacceptable.

Cancer risk from HCl facilities is six times EPA's unacceptability benchmark which is 100-in-1 million. Still, EPA should strengthen its policy and recognize that 100-in-1 million is far too high to be considered acceptable, and that some levels of other kinds of risk should also be recognized as automatically unacceptable.

Currently available science debunks its assumption that 100-in-1 million or below is acceptable, because there is so much uncertainty built into EPA's risk assessment, and because EPA lacks information on so many pollutants. For communities overburdened by pollution, EPA's 1989 benchmark policy is especially problematic. EPA should reduce the benchmark it uses to

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[51] *See, e.g.*, SAB, Review of EPA's draft entitled, "Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing" (May 7, 2010), https://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf ("SAB May 2010") *See, e.g.*, (supporting EPA's approach and urging EPA to take a more protective scientific approach on certain issues).

[52] EPA, IRIS Process for Developing Human Health Assessments (last updated Oct. 22, 2018), https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process.

determine presumptively unacceptable cancer risk, and should start recognizing that particular levels of chronic non-cancer and acute risks must also be deemed presumptively unacceptable.

EPA should recognize that cancer risk from a major industrial source category of toxic air pollution (listed under CAA § 7412) that is 100-in-1 million or less cannot be presumed safe or "acceptable." Since 1990, however, EPA has made this assumption. EPA based this assumption not on scientific information about cancer risk, but on an unusual study of people's perceptions of their own risk from 1988, known as the Survey of Societal Risk (July 1988), to consider various types of health risks at that time.[53] Using a comparison of cancer risk to other kinds of hazards Americans then faced in their daily lives, EPA effectively chose a number out of a hat that it would consider acceptable. EPA looked at an odd collection of risks, such as dangers from driving a car, and found that "the presumptive level established for MIR [maximum individual risk of cancer] of approximately 1 in 10 thousand is within the range for individual risk in the survey, and provides health protection at a level lower than many other risks common 'in the world in which we live.'"[54]

EPA has failed to revisit or update this number for the decades since, even though scientists have made breakthroughs on early-life exposure and children's vulnerability; biomonitoring and other data on adult body burdens of chemicals; the vulnerability of overburdened communities, including socioeconomic disparities; and on ways to analyze and control the impacts of pollutants on human health.

As an additional problem, EPA's current policy does not presumptively recognize any level of chronic non-cancer or acute risk as unacceptable. This is similarly outdated and EPA should determine that all such risk above the HQ of 1 is presumed to be unacceptable, unless EPA can provide a reasoned explanation for finding otherwise.

LANDMARKS SINCE 1990

- In 1990, the Clean Air Act Amendments required new basic stringency requirements for technology-based control for hazardous air pollutants and added an additional review of residual health risk to ensure protection of communities.[55]

- In 1993, the National Research Council published *Pesticides in the Diets of Infants and Children*, finding that children are not little adults, and have greater exposures and susceptibility.[56]

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[53] Survey of Risks, Benzene Rule Docket No. OAQPS 79-3, Part I, Docket Item X-B-1 (cited at Nat'l Emission Standards for Hazardous Air Pollutants; Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants, 53 Fed. Reg. 28,496, at 28,512/3-13/3 (July 28, 1988)).
[54] 54 Fed. Reg. at 38,046/1-2.
[55] 42 U.S.C. § 7412, 1990 Amendments.
[56] National Research Council, *Pesticides in the Diets of Infants and Children* (1993), https://www.nap.edu/catalog/2126/pesticides-in-the-diets-of-infants-and-children; *see also* Barton H., et al.,

- In 1994, President Clinton signed Executive Order 12898 on Environmental Justice.[57]

- In 1996, Congress enacted the Food Quality Protection Act and the Safe Drinking Water Act amendments, which explicitly require consideration of the susceptibility of children and vulnerabilities due to early exposure.[58] This same year, EPA announced a new National Agenda to Protect Children's Health.

- In 1997, President Clinton issued the Children's Environmental Health Executive Order (No. 13045) on the need to address risks to children.[59]

- In 2000, EPA first published *America's Children and the Environment*, which it has since updated.[60]

- In 2006, EPA issued new guidance on protecting children from environmental health risks as part of the rulemaking process.[61] Among other things, this Guide[62] recognized the problem of disproportionate risk to children because they may be more sensitive to pollution and exposed at a higher rate than adults because of their developmental stage. This Guide also recognized the need "to think in terms of the

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Assessing Susceptibility from Early-Life Exposure to Carcinogens, 113(9) Envtl. Health Persp. 1125 (2005); Hattis, D., et al., *Age-Related Differences in Susceptibility to Carcinogenesis: a Quantitative Analysis of Empirical Animal Bioassay Data*, 112(11) Envtl. Health Persp. 1152 (2004).

[57] Exec. Order No. 12898.

[58] 21 U.S.C. § 346a(b)(2)(C) (requiring that, in taking certain actions on pesticides "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure *shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children*") (emphasis added); 42 U.S.C. § 300g-1(b)(1)(C) (requiring that, in selecting unregulated contaminants for consideration, EPA "shall take into consideration, among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as *infants, children, pregnant women*, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.") (emphasis added); *id.* § 300j-18(a)(1) (requiring EPA to "identify groups within the general population that may be at greater risk than the general population of adverse health effects from exposure to contaminants in drinking water. The study shall examine whether and to what degree *infants, children, pregnant women*, the elderly, individuals with a history of serious illness, or other subpopulations that can be identified and characterized are likely to experience elevated health risks, including risks of cancer, from contaminants in drinking water.") (emphasis added).

[59] Exec. Order 13045, 62 Fed. Reg. 19,885 (Apr. 21, 1997).

[60] EPA, *American's Children and the Env't* (3d ed. 2013), https://www.epa.gov/ace/americas-children-and-environment-third-edition.

[61] EPA, *Guide to Considering Children's Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children* (Oct. 2006), https://www.epa.gov/sites/production/files/2014-05/documents/epa_adp_guide_childrenhealth.pdf.

[62] *Id.* at 8.

broad range of early life, pre-natal and post-natal, environmental exposures that may affect the incidence of disease or alter development."[63]

- In 2008, EPA updated the Child-Specific Exposure Factors Handbook.[64]

- In 2008 and 2009, the major National Academy of Sciences' reports – *Science and Decisions: Advancing Risk Assessment* (2009), and *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (2008) – were released, re-emphasizing the importance of addressing real-world risk to children and cumulative health risk.

- In 2009, EPA Administrator Jackson declared environmental justice and children's health as priorities.[65]

- In 2010, EPA Administrator Jackson issued *EPA's Action Development Process: Interim Guidance on Considering Environmental Justice During the Development of an Action*.[66]

- In 2011, EPA Administrator Jackson announced Plan EJ 2014, including rulemaking and science goals, to finally achieve the goals of the 1994 Environmental Justice Executive Order.[67]

- In 2016, EPA Administrator McCarthy issued Plan EJ 2020, to continue working to ensure the agency fulfills environmental justice principles to protect local communities' health and well-being, pursuant to its statutory authorities.[68]

- In 2018, the Science Advisory Board recognized that EPA needed to better support its risk assessment protocol, including for census block centroids.[69]

- In addition, in recent years, EPA's Children's Health Protection Advisory Committee has recommended addressing the developmental origins of adult disease that come from childhood exposure to air pollution and other environmental

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[63] *Id.*
[64] EPA, *Child-Specific Exposure Factors Handbook*, EPA/600/R-06/096F (Sept. 2008), https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=199243.
[65] Lisa Jackson, Remarks to the National Environmental Justice Advisory Council (July 21, 2009), https://archive.epa.gov/epapages/newsroom_archive/speeches/313ec9a2bc80d677852575fa007b3c42.html.
[66] EPA, *EPA's Action Development Process: Interim Guidance on Considering Environmental Justice During the Development of an Action* (July 2010), https://www.epa.gov/sites/production/files/2015-03/documents/considering-ej-in-rulemaking-guide-07-2010.pdf.
[67] EPA, *Plan EJ 2014*, https://www.epa.gov/environmentaljustice/plan-ej-2014.
[68] EPA, *EJ 2020 Action Agenda*, https://www.epa.gov/environmentaljustice/about-ej-2020#about.
[69] SAB, "Review of EPA's draft technical report entitled, *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*" (Sept. 13, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/0/7A84AADF3F2FE04A85258307005F7D70/$File/EPA-SAB-18-004+.pdf. SAB 2018, *supra*.

contaminants.[70] Similarly, the Committee has recommended that EPA incorporate a more robust analysis of childhood and prenatal exposure to environmental contaminants into its risk assessment method.[71]

- The Science Advisory Board has also urged EPA to address the greater risk to children from hazardous air pollution.[72] As the SAB further explained: "California's Office of Environmental Health Hazard Assessment (OEHHA) has very recently updated its methodology in ways that could affect the development of RfC and URE [unit risk estimate] values. EPA should examine these developments to make sure that the RTR process adequately covers children's risks."[73]

- Finally, during the last decade, OEHHA has also released a number of groundbreaking scientific determinations and protocols to consider and address children's health, early life exposure, and cumulative impacts, which are cited in this document, above, and are all available at http://oehha.ca.gov/. Most recently, these include three final Technical Support Documents on risk assessment and a new final Risk Assessment Manual (2015).[74]

In view of mounting scientific and societal evidence that its current approach is insufficient to protect public health, it is time for EPA scientists and science policymakers to revisit the outdated assumptions EPA makes regarding what level of cancer risk and whether some level of other kinds of risk must trigger policy interventions. EPA's own policy regarding carcinogens recognizes that they have no safe threshold of exposure. EPA has appropriately recognized that cancer risks add up to increased lifetime risk. EPA cannot reconcile what it knows – and does not know – about carcinogens with its outdated presumption that a cancer risk of 100-in-1 million or below is acceptable.

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[70] EPA, *Report of the Task Group of the Children's Health Protection Advisory Comm. on America's Children & the Env't*, (3d ed. 2010), https://www.epa.gov/sites/production/files/2014-05/documents/ace_task_group_report.pdf.

[71] Letter from Pamela Shubat, Chair, Children's Health Protection Advocacy Council, to Lisa Jackson, Administrator, EPA (Oct. 21, 2010) ("CHPAC recommends that EPA staff scientists participating in the upcoming discussions bring the concern of early life stage exposure and sensitivity to the conversations that will take place concerning optimizing risk assessment practice."), https://www.epa.gov/sites/production/files/2014-05/documents/chpac_nrc_letter_3.pdf.

[72] SAB May 2010 at 7 (stating that "an overarching concern with the Agency's chronic inhalation exposure estimates is that children's exposures do not appear to have been adequately addressed"); *see also id.* at 34 n.13 ("In particular is the question of whether the interindividual variability factor for non-carcinogens and the standard cancer unit risk derivation adequately covers children. If it does not, it is a potentially significant uncertainty given the greater intake rate of children via inhalation and sensitivity to carcinogens and other toxicants.").

[73] *Id.* at 6.

[74] *See* CalEPA, *Air Toxics Hot Spots Program Guidance Manual* (Mar. 6, 2015), https://oehha.ca.gov/air/crnr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0.

Importantly, EPA's presumption regarding cancer risk ignores the experience of communities exposed to multiple sources and types of pollution. Even if some level of risk might otherwise be acceptable, that cannot be assumed to be true for communities exposed to more than one source that is causing that level of health risk. EPA has a responsibility to address the science on cumulative impacts and risk and update its assumptions accordingly, to acknowledge that cancer risks below 100-in-1 million cannot be presumed safe.

EPA should also reform how it evaluates chronic and acute hazard indices, in which a risk number below 1 does not result in policy changes or standards, and where EPA treats risks above 1 as potentially acceptable. EPA should instead factor in uncertainties and vulnerability factors that adjust the "acceptable level of risk." This is currently done under the Food Quality Protection Act ("FQPA") when EPA uses factors to determine a Target Margin of Exposure and risks below this level warrant increased scrutiny and changes to allowable exposures.[75]

In the face of increasing evidence, which challenges the assumption of a safe or acceptable level of exposure, EPA should also consider reforming this and other risk assessments to support reducing risks to the lowest possible level, to protect public health, rather than suggesting that there is a safe or acceptable level.

III. EPA Must Set Standards That Assure an "Ample Margin of Safety to Protect Public Health" as Required by § 7412(f)(2).

EPA proposes that the existing standards for the HCl Production source category provide an ample margin of safety, and therefore proposes not to strengthen any emission standards at all to reduce toxic emissions in this rulemaking. 84 Fed. Reg. at 1584. That determination and proposed inaction are unlawful and arbitrary.

A. EPA's Determination Not to Set Standards to Assure an Ample Margin of Safety Fails to Satisfy the Statute.

Even if EPA determines that the health risks it has found from the source category are acceptable, and ignores the facility-wide risks at the acceptability step, it still must satisfy § 7412(f)(2)'s "ample margin of safety" requirement.

At the second stage of the health risk rulemaking, EPA is required to consider whether health risk and emission reductions are needed to provide an additional, "ample margin of safety to protect public health" in view of scientific uncertainty regarding its own risk assessment.[76] This provision requires EPA to set a standard that includes an "ample margin," *i.e.*, a measurable and substantial buffer or cushion, between the line of acceptability EPA draws, and the emission limit. This distinct step is important to ensure that in the event EPA's acceptability determination is not accurate as is true here (because EPA is ignoring facility-wide risk and underestimating source-

[75] *See, e.g.*, Sulfuryl Fluoride; Proposed Order Granting Objections to Tolerances and Denying Request for a Stay, Proposed Rule, 76 Fed. Reg. 3422, 3427/2-3 (Jan. 19, 2011) (explaining use of Margin of Exposure).
[76] *NRDC*, 824 F.2d at 1165; 42 U.S.C. § 7412(f)(2).

specific risk, due to the many uncertainties shown in EPA's risk assessments, as summarized here), that facilities are not allowed to emit right up to the line of what EPA believes is unacceptable. Setting the requisite "ample margin" is required to ensure that, instead, facilities emit at levels significantly lower than the level which EPA believes is acceptable, due to the dangerous nature of the chemicals emitted and the fact that some, like the carcinogens, have no truly safe level of exposure. The Act reflects the Congressional determination that the only way to protect public health is to recognize that EPA's risk assessment approach is riddled with holes and uncertainties that underestimate the risks found, as shown by the summaries of uncertainties in the proposed rule preamble, and in the draft risk assessment.[77]

The difference between the acceptability determination and the emission limit EPA must establish under § 7412(f)(2) is the "ample margin of safety" required by the Act. As the D.C. Circuit held in interpreting similar language in § 7412(d)(4), "ample margin" means something additional, and EPA cannot simply collapse these stages or say it has evaluated this when plainly it has not. *See, e.g.*, *Sierra Club v. EPA*, 895 F.3d 1, 13 (D.C. Cir. 2018) (holding that EPA had violated plain language because it has not "met the CAA requirement to include an ample margin of safety").

EPA failed to satisfy the Act's requirement because it did not consider or determine what such a margin is at all. Instead, EPA collapsed its acceptability analysis and the technology review – a separate rulemaking obligation and test – into this second and distinct step, without satisfying the statutory test. *See* 84 Fed. Reg. at 1583-84 (citing "the results of the technology review, risk assessment and other aspects of our MACT rule review"). Instead of determining what is needed to protect public health with an "ample margin of safety," EPA answers the wrong question: it addresses only "whether there are any cost-effective controls or other measures that would reduce emissions further to provide an ample margin of safety with respect to the risks associated with those emissions." *Id.*

Here, EPA did not assess any "margin of safety," much less evaluate or determine what margin would be "ample" to ensure protection of public health. The term "ample" means "more than adequate," according to Webster's Dictionary, and the D.C. Circuit.[78] The focus in section 112 is on the "individual most exposed" to a source category's emissions, and requires EPA to provide an ample margin of safety not just for anyone, but for that individual, within the most-exposed communities around these sources.[79]

EPA's failure to assess or determine an "ample margin of safety" violates the Act by ignoring and contravening its plain text. It is also unlawful and arbitrary because EPA fails to support its conclusory proposed determination and considers factors that are not part of this

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[77] *See, e.g.*, 84 Fed. Reg. at 1580-82 (acknowledging and citing examples of uncertainties which could lead to underestimates of risk); HCl RRA at 39-53; App. 2 Tech. Supp. Doc. for HEM-AERMOD Modeling at 26-31 & tbl.5-1 (Summary of General Uncertainties Associated with Risk and Technology Review Risk Assessments) (attached to risk assessments cited).

[78] See WEBSTER'S 7TH NEW COLLEGIATE DICTIONARY 31 (1971 ed.); *NRDC v. EPA*, 824 F.2d at 1153; *Envtl. Def. Fund v. EPA*, 598 F.2d at 81.

[79] 42 U.S.C. § 7412(f)(2).

statutory step, and because EPA fails rationally to support its conclusion that no changes to the standards should be made to satisfy § 7412(f)(2).

The preamble illustrates that there is no such determination in the record. Instead, EPA simply repeated the same risk information it had found to be acceptable and stated that it "considers all health factors evaluated in the risk assessment and evaluates the cost and feasibility of available control technologies and other measures." 84 Fed. Reg. at 1583. The agency merely paid lip service to the statutory language, stating without showing, that it "conducted an analysis to determine if the current emissions standards provide an ample margin of safety." *Id.* As the D.C. Circuit recognized in the Vinyl Chloride decision, at the ample margin stage under § 7412, EPA must at least consider whether uncertainties regarding its health risk assessment require a stronger standard.[80] As the court held recently in its brick kilns decision interpreting the same term ("ample margin of safety") in § 7412(d)(4), EPA must show that it has provided this margin in setting a standard, and it cannot lawfully fail to provide "any margin of safety at all."[81] EPA has failed to consider whether uncertainties in its health risk assessment for this rule, of which there are many, as cited above, require any, much less an "ample margin" of safety than simply leaving the standards at the current level. The additional information EPA states that it evaluated at this stage was "the cost and feasibility of available control technologies and other measures." 84 Fed. Reg. at 1583. EPA then went on to discuss various technologies and refer to its technology reviews. EPA has not provided information in the record to support its conclusions regarding the availability of pollution control methods.[82]

EPA has failed to follow its own recognition that § 7412(f)(2) requires it to: "protect[] the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million" and "limit[] to no higher than approximately 1 in 10 thousand [*i.e.*,

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[80] *NRDC*, 824 F.2d at 1165 ("Congress . . . recognized in section 112 that the determination of what is 'safe' will always be marked by scientific uncertainty and thus exhorted the Administrator to set emission standards that will provide an 'ample margin' of safety.").

[81] *Sierra Club v. EPA*, 895 F.3d at 13.

[82] Even if EPA had provided rational support for its conclusions, which it has not, the Act requires more than an evaluation of cost or whether additional reductions are "cost effective," which is an additional factor EPA injects that neither appears in the statute nor has been affirmed by a court. 84 Fed. Reg. at 1584. EPA failed to assess whether more health protection is required to provide an "ample margin of safety to protect public health," instead of focusing only on cost at the final step of its section 112(f) analysis. EPA's ample margin analysis is considered purely in terms of the cost of pollution reduction, without any health metric. EPA considered no additional health factors, nor determined what margin of safety, if any, would be ample. Cost is irrelevant to the question of what margin of safety is "ample." Not considering the "ample margin" in health terms writes "public health" out of the ample margin analysis, in contradiction of the statute. Finally, because this statute focuses on health, it is unlawful for EPA to consider cost at all at the "ample margin of safety to protect public health" stage. By contrast with the Supreme Court's discussion of the terms "necessary and appropriate," in recent caselaw, those terms are not used here. The economic factors in this provision are used *only* in regard to the environmental effects part of the test. EPA has given no lawful justification for considering costs in the "ample margin of safety to protect public health" stage, as opposed only to the environmental effects test, and could not do so.

100-in-1 million] the estimated risk that a person living near a plant would have if he or she were exposed to the maximum pollutant concentrations for 70 years."[83]

At the ample margin stage, EPA again refuses even to *address* the fact that the chronic noncancer risk is *above* the HQ of 1 at which harm is known to occur. EPA has found, for HCl sources, that HCl sources create, at least, a TOSHI of 2, based on allowable emissions. This is two times the harm threshold. Even if EPA could justify finding that level of risk acceptable (which it has not, as it has not even addressed it in the acceptability determination, as discussed above), it still must consider how to assure an *ample margin of safety to protect public health* from the respiratory system harm this value reflects. Yet EPA does not discuss or find that it is providing any margin, much less an ample one, to protect people from the emissions causing this risk.

Furthermore, EPA's attempt to rely on the technology review, designed to satisfy § 7412(d)(6), as a justification not to strengthen the standards to protect public health under § 7412(f)(2) is also unlawful and arbitrary. These are separate statutory tests and obligations that EPA may not lawfully collapse into one. As the D.C. Circuit explained, these are "two distinct, parallel analyses: a recurring 'technology review' under section 112(d)(6) and a one-time 'risk review' under section 112(f)(2)." *Nat'l Ass'n of Surface Finishing v. EPA*, 795 F.3d 1, 5 (D.C. Cir. 2015) (explaining that "separately" from the technology review, in the risk review, "EPA addresses . . . lingering public health risk that the initial standard did not eliminate").[84] EPA's attempt to rely on what it describes as a lack of "developments" under § 7412(d)(6) as a justification for not requiring additional standards under § 7412(f)(2) shows how inadequate and unlawful its "ample margin" determination is. It is *not* an ample margin of safety determination at all; it is just a recycled "no developments" determination.

These are separate and independent requirements, as shown by the plain text of the statute. The statute does not allow EPA to perform only a risk review rulemaking, or only a technology review rulemaking, in lieu of the other. It would violate the plain text of the Act for EPA to subjugate one requirement to another. Congress enacted each to serve a particular objective, and EPA must follow the plain language of the Act. *See, e.g.*, *Russello v. United States*, 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (citation and quotation marks omitted). The statute cannot be read in a way that would make either provision redundant. As the D.C. Circuit has held, based on the separate structures enacted and the history of the 1990 Clean Air Act Amendments, importing considerations into technology-based standard-setting under § 7412(d) "would collapse the technology-based/risk-based distinction at the heart of the Act, undermining the central purpose of the 1990 Amendments – to facilitate the near-term implementation of emission standards through technology-based solutions." *Sierra Club v. EPA*, 353 F.3d 976, 990 (D.C. Cir. 2004). Similarly, EPA may not use the technology review, designed to meet § 7412(d)(6)'s goals and requirements, to attempt to avoid satisfying the different, particular, and

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[83] 54 Fed. Reg. 38,044, 38,044-45 (Sept. 14, 1989) ("Benzene Rule").

[84] The statute directs that EPA perform the residual risk review rulemaking at least once after EPA promulgates any § 7412(d) standards, 42 U.S.C. § 7412(f)(2); the D.C. Circuit has not held that EPA must perform such a review only once for any given source category.

health-focused requirement for an "ample margin of safety to protect public health" under § 7412(f)(2).

EPA also provides no evidence at all of the technology review on which it is relying – it refers to the "results" of the technology review, but it cites no document in the record providing these results. It discusses the fact that sources use scrubbers, but it does not provide information on the kinds of scrubbers or any other details. EPA also does not discuss any other acid gas controls, or types of VOC controls or leak detection and repair, or any additional methods that it considered for these sources. EPA states that it reviewed Title V permits for these sources. None of the documents that EPA has described here appear to be in the docket.[85] Therefore, EPA has failed to provide any support for its determination, and it is unlawful and arbitrary. Furthermore, EPA cannot rely on information or documents not provided in the rulemaking docket, whether in the ample margin determination, or the technology review rulemaking. EPA's attempt to do so is unlawful and arbitrary and a violation of notice-and-comment. 42 U.S.C. § 7607(d)(3)-(7), (h).

B. EPA Must Set Standards That Protect Public Health from Cancer, Chronic, and Acute Risks With an Ample Margin of Safety.

The only additional health information EPA considers in the ample margin of safety step shows substantial risk, and yet EPA attempts to ignore these data and their import. As EPA acknowledges in the ample margin of safety section, HCl facilities are causing extremely high cancer risk – 600-in-1 million – and chronic non-cancer risk – a TOSHI of 6. 84 Fed. Reg. at 1584. The HCl sources are contributing at least 1/3 of that high TOSHI chronic risk, and yet EPA still has refused to set standards to assure an ample margin of safety.

EPA proposes to sideline these extremely high risks because they are at sources that are part of HCl facilities collocated with HCl production sources but not part of the source category under review. Thus, EPA aims to ignore this health information completely at the ample margin step for this rulemaking. EPA proposes to defer any additional action from the high-risk sources at these contiguous and commonly controlled facilities until some future time. EPA states that it

> will work with industry and state, local, and tribal air agencies as the EPA takes a two-pronged approach to address ethylene oxide emissions: (1) Reviewing CAA regulations for facilities that emit [EtO]—starting with air toxics emissions standards for miscellaneous organic chemical manufacturing facilities and commercial sterilizers; and (2) getting additional information on ethylene oxide emissions.

84 Fed. Reg. at 1584. EPA proposes to defer action and states that it "may" at some point reduce these high risks and may someday set standards to provide an ample margin of safety.

EPA's proposed ample margin determination is unlawful and arbitrary. First, even if EPA could limit its acceptability determination to the source category under review, which it cannot for the reasons discussed in the prior section of these comments, EPA cannot ignore that HCl facilities

[85] *See* Email communication from Earthjustice to EPA seeking information from the technology review (2019).

are causing *presumptively unacceptable* cancer risk in some communities. EPA must, at least, acknowledge this cancer risk is unacceptable at the ample margin stage, by comparison with its own Benzene Rule-based presumptive benchmark of 100-in-1 million. Failing to do so is ignoring its own longstanding recognition that this evidence is important at least at the ample margin of safety stage, to use the facility-wide risk assessment to protect public for the most-exposed person.

Second, EPA has failed to justify its refusal to set stronger standards to assure an ample margin of safety from these emissions, when the risks these facilities cause are unacceptable under EPA's own benchmark for cancer risk, and six times the threshold of 1 at which known harm occurs (for a broad range of chronic organ system harm). EPA recognizes that it has authority over the collocated sources that are part of regulated source categories as well. It cites specific source categories and states that "we intend to evaluate those facility-wide estimated emissions and risks further." *Id*. Here, those include, at least, the chemical manufacturing and other industrial processes that EPA identifies in the facility-wide risk assessment. *Id*. at 1583. The Residual Risk Assessment lists these facilities, and EPA well knows where they are and that they are part of various regulated air toxics source categories. *See* HCl RRA & App. 10 (listing facilities). EPA would not have included those sources in the facility-wide risk assessment if they were not "HAP-emitting operations within a contiguous area and under common control," including "all other emission sources at the facility for which [EPA] ha[s] data." 84 Fed. Reg. at 1579. EPA cannot therefore ignore these risks, or refuse to address them at all in determining what is the "ample margin of safety" needed to protect public health.

EPA's facility-wide risk data shows that it must set stronger standards for these facilities to remove all unacceptable risk and assure an ample margin of safety to protect public health. EPA should take public comment on a revised proposal that includes pollution limit reductions for ethylene oxide, TCE, Cl, HCl, and all other pollutants contributing to these high risks.

Yet at the ample margin stage, EPA does not discuss any pollution control methods or ways to consider setting any margin, much less the ample one the Act requires, to protect public health. As further discussed in Part V.D (and incorporated here), pollution control methods exist that would strengthen public health protection, and EPA must evaluate and require them to reduce the serious and unacceptable health risks the record shows.

Finally, as further discussed below, EPA has violated notice-and-comment because it has failed to provide essential underlying data it used to reach the facility-wide risk determinations. 42 U.S.C. § 7607(d)(3)-(7), (h). For example, it states that it used NEI data, but it does not provide the emissions estimates it used for any of the facilities. It gives the emissions totals for the HCl sources, but not for the facility-wide risk part of the assessment. It also gives a conclusory chart showing what it describes as the source category's contribution to the facility-wide risk, in the RRA. But it provides insufficient evidence or information showing how it reached those conclusions. Failing to provide the calculations and underlying data used to create the facility-wide risk assessment makes it impossible for the public to meaningfully comment on this. Because these risks are so high, and EPA has cited significant excess cancer cases coming from these facilities, commenters need this information and are prejudiced by EPA's refusal to disclose in the public docket.

IV. EPA's Failure to Complete a Scientifically Supported Risk Assessment Violates § 7412(f)(2) And Shows Its Proposed § 7412(f)(2) Acceptability and Ample Margin Determinations are Unlawful and Arbitrary.

To satisfy the Act, EPA must correct errors in and complete a scientifically sound health risk assessment that employs the best available science and evaluates the health risks to "the individual most exposed" to HCl facilities' emissions, as 42 U.S.C. § 7412(f)(2) requires. Absent such an assessment, EPA has underestimated health risks that these facilities create, and has failed to satisfy its legal obligation to prevent all unacceptable health risks and to assure "an ample margin of safety to protect public health," including for children and the most exposed and most susceptible communities. *Id.*

EPA's risk assessment in this rulemaking is unlawfully and arbitrarily incomplete and its determinations under § 7412(f)(2) are unlawful and arbitrary, for reasons discussed below.

A. EPA unlawfully underestimates health risk because it ignores and underestimates exposure.

1. Emissions are underreported and underestimated.

EPA's risk analysis based on the emissions inventory significantly underestimates emissions. This so-called "actual" analysis of risk is based on an emission inventory that is largely calculated from emission factors and engineering judgment. It is well-documented that emission factors underestimate emissions for a variety of reasons including inherent bias in the factors themselves and the inability to account for equipment malfunctions and environmental conditions. The agency must adjust the emissions inventory using these same conclusions from the technology review and the large body of scientific evidence, which show that emissions factors underestimate emissions, in order to ensure that the inventory better represents reality and reflects actual emissions.

While EPA did not require facilities to identify the methodology used to report emissions to the Information Collection Request ("ICR") emissions inventory, it is clear that most of the reported pollution is based on emission factors and engineering judgment. For example, EPA's Office of the Inspector General ("OIG") states that "[t]he heavy use of emission factors in the [national emissions inventory] makes the *reliability of the data highly uncertain*. Emission factors can result in emissions data of *questionable reliability* … ."[86]

Commenters believe that the emission factors used have led to underestimated emissions in part because: (1) the emission factors incorporate the erroneous assumption that equipment is operating as designed under normal conditions, and (2) the emission factors do not account for environmental variables that significantly impact emissions.

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[86] EPA OIG, *Improvements in Air Toxics Emissions Data Needed to Conduct Residual Risk Assessments* at 18 (Oct. 31, 2007), https://www.epa.gov/sites/production/files/2015-11/documents/20071031-08-p-0020.pdf (emphasis added).

The tests used to develop emission factors are intentionally conducted on new equipment operating under normal conditions because emission factors are formulas that attempt to estimate long-term average emissions.[87] EPA itself notes that "[p]arameters that can cause short-term fluctuations in emissions are generally avoided in testing and not taken into account in test evaluation."[88] Further, "[s]ources often are tested more frequently when they are new and when they are believed to be operating properly, and *either situation may bias the results*."[89] The incorporation of this erroneous assumption in the development of emission factors significantly distorts emissions data in two significant ways – neither the emissions that are generated during upset and SSM events, nor the increased emissions that result from poor maintenance of equipment are accounted for in a facility's reported emissions and emissions inventories.

Because emission factors incorporate the assumption that equipment is functioning as designed under normal conditions, emissions produced during SSM events are not accurately represented in reported emissions. The emissions from SSM events can be significant, as EPA has acknowledged. 84 Fed. Reg. at 1585 (explaining that where a source goes from 99% control to zero control due to a malfunction means that its "emissions during the malfunction would be 100 times higher than during normal operations . . . . the emissions over a 4-day malfunction period would exceed the annual emissions of the source during normal operations.").

Similarly, basing emission factors on this faulty assumption fails to accurately account for increased emissions that result from poor maintenance of equipment. Failing to assess health risks for the significant emissions produced during SSM upset events or increased emissions that result from poor equipment maintenance results in grossly inaccurate, unreliable, and biased emissions data for these sources. The emission factors do not account for environmental variables that can significantly impact emissions. Wind speed, for example, can have a substantial impact on emissions from certain sources.

2. EPA must assess and reduce health risks from emissions during upsets and malfunctions, instead of ignoring these risks.

In the proposed rule, EPA appropriately proposes the elimination of exemptions from emission limits during periods of startup, shutdown, and malfunction, as legally required under the Act and D.C. Circuit precedent. 84 Fed. Reg. at 1585. However, through the risk assessment process, EPA *is not evaluating any health risks during these periods*. Indeed, "no facility-specific analyses of [data on 'upset emissions' defined to include non-routine emissions during periods of startup, shutdown, and malfunction] were performed to characterize short-term emissions from these emission sources, and upset emissions are generally not modeled for the RTR risk assessments."[90] EPA is ignoring reality.

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[87] EPA, AP-42: Compilation of Air Pollutant Emission Factors, Vol. 1: Stationary Point and Area Sources at 4-5, https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emission-factors.
[88] *Id.*
[89] *Id.* at 2-3 (emphasis added).
[90] *See* HCl RRA, Appx. 2, Technical Support Document for HEM-AERMOD Modeling at 19.

EPA *must* account for upset emissions in modeling for risk assessments because if EPA has knowledge that a certain amount of excess pollution per year routinely escapes facilities despite existing requirements, it *must* determine how these reasonably foreseeable "upset emissions" impact public health. EPA must also consider whether changes in the existing standards could mitigate the problem and better protect the public with an ample margin of safety. It is not enough simply to point to the availability of enforcement suits by citizens or government entities.

EPA's analysis of all risks plainly ignores the additional risk from short-term emission spikes associated with upsets. EPA's own analysis shows that it continues to ignore all emissions that occur through upsets, and thus it continues to underestimate maximum short-term emissions and risk. In particular, as the Palma-Smith analysis states, EPA engaged in "data filtering," such that: "Accidental releases were dropped[.]"[91] The dropping of all so-called "[a]ccidental releases" removes most of the maximum short-term emissions numbers that EPA must consider if it indeed wishes to fulfill the Act's requirement and its own interpretation of its responsibility. EPA gives no explanation for ignoring "[a]ccidental releases," and it could give no lawful or rational basis for ignoring these emissions.

Under its own interpretation of § 7412(f)(2), EPA must assess and reduce any remaining (i.e., "residual") risk according to CAA § 112(f). 84 Fed. Reg. at 1574. It is necessary to assess "allowable" emissions because they reflect the maximum level facilities could emit without violating national emission standards. Doing so is consistent with the Science Advisory Board's recommendations.[92] Post-idling startup emissions "remain" under EPA's existing standards, and are part of the "allowable" emissions because sources may produce them without violating the standards and therefore EPA cannot ignore them. EPA's risk assessments currently ignore these risks completely, treating them as zero, when in fact they may well make the cancer risk even higher, or make the most-exposed person face a high chronic or other risk during and as a result of a malfunction.

Malfunction, upset, or so-called "accidental" events increase emissions and thereby pose increased health risks which EPA must consider. Although EPA has used the term "accidental," many such emission spikes occur as a result of events that can be prevented, and thus Commenters disagree that they are actually "accidental." Where control equipment fails for any reason, emissions could be at least 100 times greater than usual (e.g., in the circumstance where a control device has 99% efficiency, such that an uncontrolled release would cause 100 times the usual

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[91] *Id.*, Appx. 5 at 3.

[92] "The SAB found emissions estimates to be one of the most critical inputs to a residual risk assessment and an important area needing improvement. As a starting point for its assessments, EPA has proposed to use 'actual' emissions reported to the National Emissions Inventory ('NEI'), which would then be refined through internal EPA review and the public notice and comment process. However, EPA's case studies and outside evaluations suggest that the resulting emissions estimates may be biased toward underestimation. To address this concern, the Panel recommends that EPA modify its methodology to first assess residual risks associated with facility-specific 'allowable' emissions, reflecting current regulatory limits." SAB May 2010 at ii.

amount of emissions). 84 Fed. Reg. at 1585.[93] Ignoring such emissions is an unlawful and arbitrary example of the problem of ignoring health risk in the agency's assessment. The higher emissions caused by malfunction or upset emissions can accumulate and combine to increase public health impacts and lead to much higher risks for community members than those they face on a daily basis.

Failing to look at the true potential for spikes in emissions over a person's lifetime may underestimate acute risk, cancer risk and the amount of chronic non-cancer risk based on pollutants that persist in the environment. Ignoring these emission spikes is equivalent to treating additional health risk caused by exceedances as zero. The Science Advisory Board has criticized EPA's underestimation of maximum short-term emissions, and this rulemaking continues to suffer from the same flaws that SAB identified. EPA knows that there is additional risk from malfunctions and violations, and it has no lawful or scientific basis to ignore this additional risk.

EPA calls its method of calculating acute risk a "worst-case" scenario approach, and it does attempt to account for some variability in assessing health risks as shown by the use of a factor at all. However, it does not come close to modeling the actual "worst case" scenario because each such factor is too low, as it is ignoring all malfunctions which exceed the standards. Still, EPA's recognition that it is appropriate to use factors to assess higher emissions shows that the agency could simply use a more accurate factor to account for malfunctions for acute and other types of health risk in order to close the gap and respond appropriately to SAB's criticism of its current method. EPA regularly uses statistical methods and probability factors, which are readily available tools that EPA can also use to assess health risk due to malfunctions in order to set clean air standards.

To create representative factors to assess the health risk from malfunctions, EPA has information available, or can collect information, on major sources' malfunction and violation histories from the reports required under the prior rule. If EPA needs more refined data regarding these emissions to fulfill its legal obligation, EPA should simply request additional data from sources.

EPA has at least once assessed chronic and acute risk from "non-routine" or malfunction emissions – in the 2015 Petroleum Refinery Sector Rule.[94] Refusing to assess and consider the additional health risks from these incidents here would thus also be arbitrary as there can be no rational basis for recognizing the need to evaluate them in one rule but not another.

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[93] *See also* EPA HCl NESHAP RTR Proposal Cost Impacts Spreadsheet Dec. 2018, https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0417-0032 ("We assume 10% of respondants will have an SSM event that does not proceed according to the SSM plan" and that "respondants will have an average of 10 SSM events per year."); Dow Chemical Submissions to EPA on SSM Events, https://www.regulations.gov/document?D=EPA-HQ-OAR-2018-0417-0034 (reporting that for one Dow facility Pittsburg, CA, "[t]he SSM plan was followed 24 times in 2016, 64 times in 2017, and . . . 30 times in 2018 as of June 28, 2018"; that for Freeport, TX and Midland, MI: "ranges from 0 to 10 times per year").

[94] EPA, *Final Residual Risk Assessment for the Petroleum Refining Source Category*, EPA-HQ-OAR-2010-0682-0800, at 35 (Sept. 2015), https://www.regulations.gov/document?D=EPA-HQ-OAR-2010-0682-0800.

3. EPA's Assessment of Health Risks at the Census Block Centroid Violates the Act's Requirement to Protect "the Most-Exposed Individual" And Is Arbitrary.

As part of the residual risk assessment for this source category, EPA unlawfully and arbitrarily fails to assess the health risks for "the individual most exposed to emissions" from HCl facilities as § 7412(f)(2) requires. Instead, EPA has chosen an arbitrary point, a census-block centroid, without demonstrating that this is equivalent to the person "most exposed." 84 Fed. Reg. at 1576. EPA itself implicitly admits that its approach is ineffective because it made adjustments in some instances "to better represent the population in the blocks," and to "add additional receptor locations where the population of a block is not well represented by a single location." *Id*. at 1580. As EPA's Science Advisory Board explained in a 2018 report, EPA's ad hoc attempt to assess health risks to the most-exposed person is not scientifically justified.[95] EPA's failure to meet this core statutory requirement renders the proposed rule unlawful and arbitrary.

EPA's modeling understates cancer and other chronic health risk by assuming that chronic exposure to hazardous air pollutants from this source occurs at the census block centroid and *not* at the facility fence or property line, even though people do live in those locations. According to the risk assessment document, EPA "use[d] the estimated annual average ambient air concentrations of each HAP emitted by each source in the source category. The HAP air concentrations at each census block centroid … are a surrogate for the chronic inhalation exposure concentration for all the people who reside in the census block." 84 Fed. Reg. at 1576.

Census block centroids are insufficient as a matter of science and do not satisfy EPA's duty to assess health risks and protect the "most exposed" individual as required by § 7412(f)(2). EPA's current modeling approach understates cancer and other chronic health risks by assuming that chronic exposure to hazardous air pollutants from a facility occurs at the census block centroid and *not* at the facility fence or property line, even though people often do live or spend significant time at or near those locations. For risks from HAP emissions, no scientific effort has been made to move receptor points closer to the facility to assess chronic or cancer risk, even in those instances where local residents live nearer to a facility than the geographic centroid of the census block. This conflicts with the recommendation of the Science Advisory Board, which has urged EPA to consider "specific locations of residences."[96]

Even in its current review, the SAB has found that EPA's report "does not provide enough information about the tool, especially regarding criteria that would determine the number and placement of new receptors."[97] Like the SAB panel, Commenters are concerned that EPA's

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[95] SAB, "Review of EPA's draft technical report entitled *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*" (Sept. 13, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/0/7A84AADF3F2FE04A85258307005F7D70/$File/EPA-SAB-18-004+.pdf.

[96] SAB May 2010.

[97] SAB, "Review of EPA's draft report entitled *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*" (Sept. 13, 2018),

method is not scientific or lawful, would not be reproducible, and that application would vary should a different risk assessor conduct modeling on an individual facility. It is imperative that the EPA has verification metrics in place to ensure that it assesses health risks based on the actual or likely locations of specific receptors representative of those living near the facility and/or who are the people most exposed to a source or source category.

Taking geographic variation out of the equation fails to properly account for exposure to the "individual most exposed to emissions" as required by section 7412(f)(2)(A), and fails to provide an accurate accounting of risks. Estimating the annual average concentrations at the area-weighted centers of census blocks blatantly and artificially underestimates the risk estimated for people at the fence-line since the center of a census block is almost always further away from the facility than the fence-line. Census blocks vary greatly in size, especially outside of large urban areas, yet EPA provides no evidence that it reviewed census block size or configuration to consider how concentrations of pollutants might vary within these blocks. Therefore, area-weighted centers of census blocks likely significantly underestimate exposure in some cases. By failing to assess health risks for the most-exposed person (rather than just by the middle of a census block) EPA violates this provision.

EPA's failure to adjust receptor points for residents living on the fence-line is particularly inexcusable given that the HEM-AERMOD system allows for such an adjustment, and that such an adjustment was appropriately made for the estimation of acute health risks.[98] Having recognized that the maximum exposed individual for acute risks is likely present at the fence-line, EPA cannot justify failing to analyze cancer and other chronic health effects in a similar manner.

B. EPA's Assessment Ignores and Fails to Apply The Best Available Science to Evaluate Vulnerability and Real-World Health Risks for Exposed Communities.

EPA must account for the health risks it is ignoring and recognize that scientific knowledge points to greater health risks than the agency has found. EPA is not yet following the best available and most current science to address the real-world health risks for the individual most exposed to HCl sources and facilities at issue in this rulemaking. EPA must finally act to apply this science in this rulemaking and all other health risk rulemakings under the Clean Air Act under § 7412(f)(2).

In particular, EPA has no valid excuse not to follow the recommendations of the National Academy of Sciences and its own Science Advisory Board on the below-discussed key issues that affect the most-exposed and most vulnerable populations, especially children, people of color, and low-income people.

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https://yosemite.epa.gov/sab/sabproduct.nsf/0/7A84AADF3F2FE04A85258307005F7D70/$File/EPA-SAB-18-004+.pdf.

[98] 84 Fed. Reg. at 1577 (stating that EPA evaluated acute exposures and risks at "the point of highest off-site exposure to assess the potential risk to the maximally exposed individual," *i.e.*, not just the census block centroids).

California's OEHHA has addressed most of the scientific developments described below, particularly the explicit consideration of infants and children; EPA has no reasonable basis not to do the same. In particular, OEHHA is now applying final scientific technical support documents to update its *Air Toxics Hot Spots Program Guidance Manual* (2015).[99] Those scientific documents and the new manual provide a clear roadmap that EPA can and should use to close major gaps in its consideration of health risks from air toxics sources.

As further explained below, EPA must consider the science, and update and strengthen its risk assessment in, at least, each of the following ways before finalizing the rule:

- Account for individual-level vulnerability in this risk assessment by better incorporating the vulnerability of children, early-life exposures, and the developing fetus into risk assessment methods:
    - Prenatal susceptibility: Account for increased susceptibility by using a prenatal adjustment factor for all carcinogens of *at least a factor of 10X* (similar to the 10X Age Specific Factor applied to the prenatal life stage by California EPA scientists).
    - Account for increased susceptibility by using age-dependent adjustment factors for all carcinogens, not just known mutagens.
    - For chronic non-cancer risk, consult and apply child-specific reference values (such as those created by California EPA scientists), where available.
    - If child-specific reference values are unavailable, consult science on early exposure impacts, and use an additional default factor of *at least 10X*.
- Account for vulnerability due to residence in a community that is highly exposed, by including factors to account for increased vulnerability based on demographic differences identified in the companion document, *Analysis of Socio-Economic Factors For Populations Living Near Portland Cement Manufacturing Facilities*, as part of the risk assessment. EPA also must fully integrate the findings of its environmental justice analyses into this risk assessment and rulemaking, and set stronger pollution limits to provide environmental justice. EPA's proposal to ignore the disproportionate impacts to communities of color and low-income people from these facilities is arbitrary. The agency's refusal to recognize the increased health risks due to disproportionate exposure violates the Act's requirement for a health risk assessment that assures an "ample margin of safety to protect public health." 42 U.S.C. § 7412(f)(2).

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[99] *See* CalEPA, *Air Toxics Hot Spots Program Guidance Manual* (Mar. 6, 2015), https://oehha.ca.gov/air/crnr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0. This manual combines the critical information from the three Technical Support Documents, finalized in 2008, 2009, and 2012 into a guidance manual for the preparation of health risk assessments. *Id.* Each of these final Technical Support Documents are also attached in the Appendix.

- Assess the cumulative burden of exposures to multiple pollutants and sources via multiple pathways:
    - Assess and aggregate exposure from multiple pathways – including by adding inhalation and non-inhalation-based cancer risks.
    - Include the interaction of multiple pollutants.
    - Account for exposure to multiple sources. Until EPA has a specific mechanism for estimating total exposures, a default or uncertainty factor of at least 10X should be used to provide overburdened communities with the protection they need now.
    - Account for cumulative impacts of multiple exposures and vulnerabilities by shifting the level of risk which triggers policy action.
- Reduce EPA's benchmark of what it considers acceptable lifetime cancer risk instead of relying on the outdated upper limit of 100-in-a-million.
- In the face of increasing evidence calling into question the assumption of a safe or acceptable level of exposure, EPA should also consider changing its approach to risk assessment to support reducing risks to the lowest possible level to protect public health, rather than suggesting that there is always a safe or acceptable level. As EPA itself has recognized, there are many uncertainties suggesting its risk assessment is an underestimate and only addresses part of the picture.

EPA has no reasoned explanation for not applying the current science to address each of the above problems with its current risk assessments. And, EPA has no valid basis for ignoring the science from experts such as the National Academy of Sciences ("NAS"), Science Advisory Board, and other expert regulators, such as California EPA's OEHHA. EPA must direct its staff to apply the best scientific evidence and tools currently available on risk assessment.

Under § 7412(f)(2), it would be both unlawful for EPA to ignore the health risks that it knows that the HAPs emitted by HCl facilities can cause and it would be arbitrary and capricious for EPA to avoid applying the best available science here. It also would be unacceptable and unjust for EPA to ignore the current scientific and regulatory tools available for communities bombarded by toxic air pollution. If EPA wishes to act on its stated commitment to environmental justice, it should finally start to use the science available now to address these impacts and risks, while also working to continue to update its risk assessment approaches.

Commenters have attached many of the health impact and risk documents cited in these comments as part of an accompanying Appendix, but not all, because EPA has those not attached already available before the agency in many different specific rulemaking dockets and/or in the EPA Office of Science Advisor docket on the Request for Information on Cumulative Risk ("CRA") Assessment, EPA-HQ-ORD-2013-0292. These Comments incorporate all of the previously submitted scientific documents on these issues by reference.

1. EPA underestimates chronic non-cancer risk from hydrochloric acid.

The 2000 Cal. EPA OEHHA value should be used to assess chronic non-cancer risk, instead of the 1995 IRIS value which EPA described as "low confidence." *Sierra Club v. EPA*, 895 F.3d at 11-12. That was a value IRIS created that it had stated it planned to update when additional data became available, but that update has not occurred. In such circumstances, EPA's own prioritization policy directs it to use the best available science, which would include the Cal. EPA OEHHA value. Due to EPA's low confidence in its outdated IRIS value for HCl from 1995, the D.C. Circuit has held that EPA cannot ignore and should use the Cal. OEHHA value for hydrogen chloride, which is more protective of public health – 9 μg/ m^3 or 0.009 mg/ m^3 (instead of 0.02 mg/ m^3 which is what EPA proposes to use here).[100]

The 1995 IRIS assessment relied on two principal and supporting studies dated from 1985 and 1982, respectively. In addition to the "low" confidence rating determined by both internal and external reviewers, the studies themselves were based on limited findings, specifically one study which used only one dose level and the supporting study being based on subchronic bioassays. The OEHHA technical support document for HCl relied on the same principal study and determined that humans are more susceptible to the effects observed. The resulting reference exposure level is more protective than EPA's 1995 value, which was incomplete, and in which EPA had "low confidence," when originally created. As EPA's longstanding policy shows, OEHHA's value meets EPA's consistency, reliability, and peer-review qualifications and should be used.

2. EPA underestimates chronic health risks by refusing to recognize that chronic (non-cancer) risk-causing pollutants have no safe level of exposure.

NAS recommends that cancer and chronic non-cancer risk assessment use the same approach in order to address the fact that very low levels of non-carcinogen exposures can pose health risks.[101]

The use of reference doses ("RfDs") for dose-response risk assessment of chronic non-cancer health effects may significantly underestimate risk according to NAS.

For these health effects, risk assessments focus on defining the reference dose or reference concentration ("RfC"), which is defined as a dose "likely to be without an appreciable risk of deleterious effects" over a lifetime of exposure. In fact, these levels may pose appreciable risks.[102]

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[100] Cal. OEHHA, Hydrogen Chloride, https://oehha.ca.gov/chemicals/hydrogen-chloride; https://oehha.ca.gov/media/downloads/crnr/appendixd3final.pdf (pp. 309-312 attached); HCl RRA at 35.
[101] NAS, *Science and Decisions: Advancing Risk Assessment* at 265-66 (2009), https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment ("NAS 2009") .
[102] NRDC, *Strengthening Toxic Chemical Risk Assessments to Protect Human Health* at 10 (Feb. 2012), http://www.nrdc.org/health/files/strengthening-toxic-chemical-risk-assessments-report.pdf (citation and quotation marks omitted)..

For this reason, EPA should follow the NAS recommendation to use similar approaches for chronic non-cancer as for cancer risk assessment, which assumes deleterious health effects for any amount of exposure.

Traditional toxicology risk assessment is a method developed for engineering but is very poor for assessing the biological complexities of human health. Most government and industry scientists that study environmental contaminants are not physicians, but rather toxicologists. In recent years, the medical community has increasingly parted ways with toxicologists regarding the health consequences of environmental and chemical toxins. For 400 years the foundation of toxicology has been the concept of "the dose makes the poison," which is a presumption that health effects are related to dose, and that a dose can be found for virtually all chemicals where no effect is found. As reassuring as that thought may be, it no longer holds up to scientific scrutiny.

Molecular biologists and epidemiologists are now pointing out two important contradictions to this pillar of toxicology. The greatest public health threat of chemicals is for fetal exposure for which the dose may be less important than the timing, i.e., the presence of a toxic chemical alone, during a critical window of embryonic development, has been shown to cause severe teratogenic effects or even fetal death. The second contradiction is the idea that the smaller the dose, the less effect. Scientists are now discovering that for some toxic chemicals, the clinical effect can actually increase as the chemical concentration decreases and that there is no safe level of exposure.

Prominent medical societies are now publicly disputing the assumption of safe levels of exposure for toxic agents like endocrine disruptors. Polycyclic aromatic hydrocarbons ("PAHs") are now known to act as endocrine disruptors. A 2009 statement by the Endocrine Society, the largest organization of internal medicine physicians that specialize in endocrine and hormonal diseases, made this statement regarding endocrine disruptors and their potential harm to fetal development:

> [E]ven infinitesimally low levels of exposure – indeed, any level of exposure at all – may cause endocrine or reproductive abnormalities, particularly if exposure occurs during a critical developmental window. Surprisingly, low doses may even exert more potent effects than higher doses.[103]

The extraordinary vulnerability of *in utero* development makes reducing toxic air emissions an urgent public health matter. This risk was specifically addressed by a recent joint public statement by the American College of Obstetricians and Gynecologists and the American Society for Reproductive Medicine. The position statement included this:

> Reducing exposure to toxic environmental agents is a critical area of intervention for obstetricians, gynecologists, and other reproductive health care professionals. Patient exposure to toxic environmental chemicals and other stressors is ubiquitous, and preconception and prenatal exposure to toxic environmental agents can have a profound

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[103] The Endocrine Society, *Endocrine-Disrupting Chemicals* at 4 (June 2009), https://www.endocrine.org/-/media/endosociety/files/publications/scientific-statements/edc_scientific_statement.pdf?la=en.

> and lasting effect on reproductive health across the life course. Prenatal exposure to certain chemicals has been documented to increase the risk of cancer in childhood...[we] join leading scientists and other clinical practitioners in calling for timely action to identify and reduce exposure to toxic environmental agents while addressing the consequences of such exposure.[104]

A recent panel of twelve national endocrine disruptor specialists wrote a review of the medical literature and made this comment: "[for] every chemical that we looked at that we could find a low-dose cutoff, if it had been studied at low doses it had an effect at low doses."[105]

Finally, a report published in The New England Journal of Medicine, regarding the toxicity of volatilized compounds from oil made these important statements illustrating the risk from small exposures to toxic agents.

- "Mutagenic effects theoretically can result from a single molecular DNA alteration. Regulatory prudence has led to the use of 'one-hit models' for mutagenic end points, particularly cancer, in which every molecule of a carcinogen is presumed to pose a risk."

- "Pregnant women should particularly avoid dermal contact with oil and should avoid areas with visible oil contamination or odors."[106]

The scientific and medical community's growing recognition of this science illustrates the exquisite sensitivity that the developing fetus has to toxic agents at extremely small doses, and the fact that EPA needs to evaluate non-cancer chronic risk similarly to cancer risk, with the recognition that there is no safe level of human exposure.

3. EPA has underestimated cancer and chronic (non-cancer) health risks by failing to account for increased vulnerability and variability in early life and based on other relevant factors.

EPA is legally required to assess the health risks to the "individual most exposed" to these sources' emissions. 42 U.S.C. § 7412(f)(2). EPA's failure to account for vulnerability and variability based on the current science, particularly the science addressing early-life and

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[104] American College of Obstetricians and Gynecologists Committee on Health Care for Underserved Women, American Society for Reproductive Medicine Practice Committee, Committee Opinion No. 575, Exposure to Toxic Environmental Agents (Oct. 2013, reaffirmed 2018), http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Exposure-to-Toxic-Environmental-Agents.

[105] Vandenberg, L., *Low-Dose Effects of Endocrine Disruptors, with Laura Vandenberg*, Envtl. Health Perspectives (June 2012), https://ehp.niehs.nih.gov/trp060112/; Vandenberg L., et al., *Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses*, 33 Endocrine Reviews 378 (June 1, 2012).

[106] Goldstein B., et al., *The Gulf Oil Spill*, 364 New England Journal of Medicine 1334, 1335, 1339 (Apr. 7, 2011).

socioeconomic factors in the risk related to exposure, has led EPA to underestimate the health risks that these sources cause to the most-exposed individuals.

First, the National Academy of Sciences ("NAS") report and other new scientific and policy developments, as discussed there and in these comments, direct that EPA must better account for vulnerability and variability.[107] In particular, the science is now clear that "children are not 'little adults'" when it comes to toxic chemicals.[108] They are both susceptible to greater harm from exposure to toxic chemicals, because they are still growing and developing, *and* they are exposed to such chemicals at a greater rate than adults because of age-specific behaviors and physiological characteristics.

Second, EPA must also better account for other types of human variability because some people exposed to the same amount of a pollutant experience greater health risk due to other factors, such as genetics and baseline health status. Socioeconomic status has been shown to act as a proxy for other types of human variability to chemical risk that EPA has not adequately addressed in its draft risk assessments for this proposal. EPA's demographic analysis is important, and shows the need for EPA to evaluate the impact of disproportionate exposure and health risks for certain demographic groups in the context of the risk assessment as well as acknowledging the disparities exist, as it has appropriately done.

This section discusses key ways in which EPA must better address both the greater risk to children (including from early-in-life exposure to toxic chemicals), and other important types of human variability. Summarized at the end of this document are the currently available scientific and policy developments on children's health and environmental justice that illustrate the need for updates to EPA's risk assessment approach.

a. Cancer: Account for increased early life susceptibility by using age-dependent adjustment factors for all carcinogens.

EPA's cancer risk assessments for these sources do not adequately account for early-life exposure or the greater risk to and susceptibility of children. EPA must follow the science and account for increased early-life susceptibility by applying age-dependent adjustment factors for *all carcinogens* emitted.

EPA has restricted its application of age-dependent adjustment factors, as discussed in the 2005 *Guidelines* and the *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*, to those HAPs included in EPA's list of carcinogens that act by a mutagenic mode of action.[109] EPA therefore has not applied age-dependent adjustment factors to

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[107] NAS 2009.
[108] National Research Council, *Pesticides in the Diets of Infants and Children* at 3 (1993), https://www.nap.edu/catalog/2126/pesticides-in-the-diets-of-infants-and-children.
[109] *See* EPA, *Guidelines for Carcinogen Risk Assessment*, EPA/630/P-03/001B001F at 1-19 to 1-20 (Mar. 2005), https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf ("2005 Guidelines"); EPA, *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*, EPA/630/R-

assess cancer risk from all of the carcinogens emitted by these sources. The NAS recognized this as a "missing" default in EPA's approach that it should address and account for.[110]

EPA must follow the science showing the need to use age-dependent adjustment factors for all carcinogens.[111] Because OEHHA has provided robust scientific support for this approach, using these factors to assess cancer risk for all carcinogens would be consistent with the NAS recommendations. As the NAS explained in 2009: "EPA needs methods for explicitly considering in cancer risk assessment ... chemicals that do not meet the threshold of evidence that the agency is considering for judging whether a chemical has a mutagenic mode of action … . Special attention should be given to hormonally active compounds and genotoxic chemicals that do not meet the threshold of evidence requirements."[112]

The 2005 *Guidelines* recognized that updates would be needed if more data become available.[113] Now that such data are available, including from the NAS and OEHHA, the agency must update its approach and implement age-dependent adjustment factors for all carcinogens.[114]

b. Cancer: Prenatal susceptibility: Account for increased susceptibility to prenatal exposures by using prenatal adjustment factors for all carcinogens.

EPA's risk assessments also do not take into account increased susceptibility to carcinogens due to prenatal exposures, even for known-to-be mutagenic carcinogens.

The 2005 *Supplemental Guidance* recognized the scientific findings of increased susceptibility to carcinogens resulting from prenatal exposure, but did not develop adjustment factors to account for increased cancer risk resulting from prenatal exposures.[115] For example, EPA recognized that "[e]xposures that are of concern extend from conception through adolescence

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03/003F (2005), https://www.epa.gov/sites/production/files/2013-09/documents/childrens_supplement_final.pdf ("Supplemental Guidance").

[110] NAS 2009 at 196 tbl.6-3.

[111] CalEPA, Technical Support Document for Cancer Potency Factors: Methodologies for Derivation, Listing of Available Values, and Adjustments to Allow for Early Life Stage Exposures at 3-4, 50-51 (May 2009) ("TSD for Cancer Potency Factors"), https://oehha.ca.gov/media/downloads/crnr/tsdcancerpotency.pdf and https://oehha.ca.gov/air/hot_spots/tsd052909.html.

[112] NAS 2009 at 112 tbl.6-3 (describing the fact that "*in utero* periods and nonmutagenic chemicals were not covered" by EPA's 2005 guidelines, as significant omissions).

[113] *See* Supplemental Guidance at 21, 31 ("EPA expects to expand this Supplemental Guidance to specifically address modes of action other than mutagenicity when sufficient data are available and analyzed.").

[114] CalEPA, TSD for Cancer Potency Factors. EPA should also update the 2005 Guidelines to fully reflect current science as described in OEHHA's 2009 review of the scientific literature on increased susceptibility to carcinogens from early life exposures.

[115] Supplemental Guidance at 4-5, 14 & tbl.1a (discussing research on human and animal cancer risks from prenatal exposure).

and also include pre-conception exposures of both parents."[116] The NAS identified the lack of accounting for "*in utero* periods" of exposure as a major omission in EPA's 2005 cancer guidelines.[117]

OEHHA conducted its own review of the scientific literature to account for prenatal susceptibility and exposures, which EPA should also consult and apply in its assessments.[118] It has also developed methods and adjustment factors to account for prenatal susceptibility and exposures that EPA should use.[119] In its risk assessment guidelines and risk assessment manual, OEHHA includes procedures for exposure assessment during fetal development, which EPA should evaluate.[120] OEHHA specifically discusses the use of a 10X adjustment factor for cancer risk to account for prenatal (third trimester) to age 2 exposures, and EPA should consider using this same factor.[121]

EPA should consult the science OEHHA has used to develop this well-supported factor, and should then use at least a 10X adjustment factor for all carcinogens to assess health risk due to prenatal exposure.

As EPA's rules are insufficient to protect humans at the critical stage of embryonic development, they simply are failing to protect public health. Exposure to toxic agents in the intrauterine stage of life has one of the most important impacts on lifelong health, and can be irreversible.

c. Chronic non-cancer risk: Where child-specific reference values are unavailable, EPA must consult science on early exposure impacts and use an additional default or uncertainty factor.

The increased susceptibility of children, while known to exist, has not been quantified for many toxic chemicals. Until EPA has child-specific or child-based reference values available for a given pollutant, EPA should apply a default or uncertainty factor of at least 10 to account for increased risk from early-life exposures for non-cancer risk in this rulemaking and other risk assessments.

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[116] 2005 Guidelines at 1-16.
[117] NAS 2009 at 112-13; *see also id.* at 112, 196 (noting that it is a "missing" default that EPA recognizes *in utero* carcinogenic activity, but fails to take account of it or calculate any risk for it as "EPA treats the prenatal period as devoid of sensitivity to carcinogenicity").
[118] *See* CalEPA, TSD for Cancer Potency Factors appx.J, https://oehha.ca.gov/media/downloads/crnr/appendixjearly.pdf.
[119] *Id.* appx.J at 7-8 & tbl.1.
[120] *See* CalEPA, *Air Toxics Hot Spots Program Risk Assessment Guidelines: Technical Support Document for Exposure Assessment and Stochastic Analysis* at 1-6 to 1-7 (Aug. 27, 2012), https://oehha.ca.gov/air/crnr/notice-adoption-technical-support-document-exposure-assessment-and-stochastic-analysis-aug ("OEHHA 2012 Guidelines").
[121] *See id.*; Air Toxics Hot Spots Program Guidance Manual at 2.

This would be consistent with the NAS recommendation on the need for EPA to use default factors to account for greater risk,[122] with the science developed and considered by OEHHA, and with the 10X factor enacted by Congress in the Food Quality Protection Act. Specifically, as the SAB report explained:

> California EPA/OEHHA has determined that inhalation dosimetry for children is sufficiently different from adults to warrant a full 10-fold intra-individual pharmacokinetic uncertainty factor (i.e., an extra 3-fold PK uncertainty for children relative to the IRIS method) as a default approach. In setting non-cancer reference exposure levels (RELs), Cal EPA/OEHHA also considers that children may be outliers in terms of chemical susceptibility and on a case-specific basis adds a children's pharmacodynamic factor of 3-fold, making the inhalation risk for children as much as 10 times greater than adults.[123]

In addition, Congress has recognized this science in its unanimous vote on toxics legislation passed in 1996 – the Food Quality Protection Act ("FQPA") – in which Congress found the need to use, and enacted, a tenfold Margin of Safety, or "10X factor." Specifically, the Act provides that "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children."[124] Congress's recognition of the need to use this default factor provides a model that EPA should consider and incorporate into its residual risk assessment.

It would be appropriate and within EPA's authority under Clean Air Act section 7412(f)(2) to determine that EPA must similarly use a children's tenfold margin of safety factor here, to fulfill the Clean Air Act's "margin of safety" requirement.[125] In doing so, EPA may rely directly on the science itself, and also on the unanimous guidance from Congress, provided in the FQPA, that the existing evidence of increased harm requires significant action to protect children from toxic exposure.

Further, the child-specific reference doses that OEHHA has created for some pollutants provide support for the use of an additional tenfold margin of safety factor. EPA's current reference values are generally one order of magnitude less protective (i.e., larger) than the values that California has recognized as needed to protect children, based on the currently available science and a specific assessment of research relevant to early life exposures.

EPA can have no valid basis for ignoring science showing that pollutants other than carcinogens also can cause substantial harm even at low doses if exposure occurs *in utero* and during the early windows of vulnerability.

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[122] NAS 2009 at 190-93, 203.
[123] CalEPA, TSD for Cancer Potency Factors at 3-4, 50-51.
[124] 21 U.S.C. § 346a(b)(2)(C) (requiring that, in establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, "for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied" to protect infants and children).
[125] 42 U.S.C. § 7412(f)(2).

d. Account for increased vulnerability based on demographic differences, as part of the risk assessment.

The NAS report also identified significant flaws in EPA's assessment of individual variability in risk assessments, like this rule, that could result in significant underestimation of risk, including in regard to socioeconomic differences. In particular, EPA must fully account for the fact that people can be more vulnerable to toxic pollution due to various physiological, societal, demographic, and exposure history differences, and can therefore experience greater health risk from the same amount of a toxic chemical exposure.[126] As the NAS has observed, performing risk assessment that is meaningful for communities that already face a significant amount of pollution and for communities concerned about environmental justice "requires an ability to evaluate multiple agents or stressors simultaneously—to consider exposures not in isolation but in the context of other community exposures and risk factors."[127] Addressing this issue is particularly important for EPA because of the need to consider and address environmental justice as mandated by Executive Order 12898.

EPA found disparity in the risks that these sources create, with disproportionate exposure and thus risks, falling on people of color including Blacks or African Americans, and people living below the poverty level. 84 Fed. Reg. at 1583.

Communities that have minority and lower income populations and communities with higher than average levels of cancer, and respiratory and other health problems, as well as a lack of access to health care, are likely to be more vulnerable to the impact of toxic air pollution.[128] Because these sources, and thus EPA's rule regulating them, affect communities that are disproportionately minority or lower income, EPA cannot ignore this greater risk in its assessment.

As a key starting point, EPA must assess the greater health risk based on socioeconomic status found in epidemiological research studies.[129] As the NAS recognized, "there is growing

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[126] *See, e.g.*, NAS 2009 at 135-39, 145-51 (explaining that "[h]ow the population responds to chemical insults depends on individual responses, which vary among individuals"; and "[i]f the sensitive people constitute a distinct group either because of their numbers or because of identifiable characteristics—such as ethnicity, genetic polymorphism, functional or health status, or disease—they should be considered for separate treatment in the overall risk assessment"); *id.* at 112 (noting that EPA's guidelines do not address variability due to factors "such as age, ethnic group, socioeconomic status, or other attributes," and explaining that "there is a need for a nonzero default to address the variation in the population expected in the absence of chemical-specific data"); *see also id*. at 134 (discussing various factors and recommending that "much more emphasis needs to be placed on describing the ranges of susceptibility and risk"); *see also id.* at 177-82, 196.

[127] *Id*. at 214-15.

[128] *See, e.g.*, Chari R., et al., *Integrating Susceptibility into Environmental Policy: An Analysis of the National Ambient Air Quality Standard for Lead*, 9 International Journal of Environmental Research and Public Health 1077, 1078 & nn.5-10 (citing research); *see also* CalEPA, Cumulative Impacts: Building a Scientific Foundation at 6, 10, 12-17 (Dec. 2010).

[129] NAS 2009 at 109-10 & tbl.4-1 (describing the need to consider increased susceptibility due to prior and concurrent exposures; and to "social and economic factors"); *id.* at 220-21 (describing ways to assess

epidemiologic evidence of interactions between environmental stressors and place-based and individual-based psychosocial stressors, driven in part by the spatial and demographic concordance between physical and chemical environmental exposures and socioeconomic stressors," and there is also a growing field of information on social epidemiology, which addresses the relationship between social factors and disease in human populations.[130] Data describing these factors are available from the Center for Disease Control's Environmental Public Health Tracking ("EPHT") Program, the U.S. Agency for Toxic Substances and Disease Registry, state and local health agencies, and academic researchers,[131] and EPA must consider and use such information in its risk assessment.

Further, EPA must recognize and evaluate the need to consider socioeconomic factors not only as part of an environmental justice analysis, but also as part of EPA's consideration of both vulnerability and variability, as core elements of the risk assessment itself. EPA has been assessing the demographics of affected communities, pursuant to CAA § 7412(f) and Environmental Justice Executive Order 12898.[132] This is necessary and important to continue. However, in addition to looking at the demographic census data on race, ethnicity, poverty level, and similar factors, EPA must also assess the starting point or baseline overall health status of the affected individuals and communities using the best available data at a local and national level, including the baseline cancer levels, respiratory problems, and health problems associated with the toxic chemicals emitted by a source category. Doing so would be consistent with the 1999 Residual Risk Report.[133] It would also follow EPA's own statements in the 2014 *Second Integrated Urban Air Toxics Report* that more work is needed to reduce excess cancer risks in urban areas that continue to face elevated risks.[134]

Thus far, EPA has failed to adequately assess human variability, particularly the increased vulnerability of different socioeconomic groups, or to incorporate the information gained from the environmental justice analysis into its risk assessment. In this rulemaking, EPA has recognized that there are disproportionate impacts, e.g., on Blacks, people of color, and low-income people (living below the poverty level). But EPA has not considered the existing health burden at all in affected communities, or the greater vulnerability to toxic air pollution of the particular demographic groups EPA acknowledges are exposed. This is unlawful because it means EPA has

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cumulative risk including by consideration of "epidemiologic concepts" and information, and by considering "what the burden of disease is in the context of simultaneous exposure to a number of stressors"); *id.* at 230 (discussing the role of epidemiology and surveillance data).

[130] *Id*. at 230-33.

[131] *Id*. at 232 (describing data available on health status, and patterns of diseases and exposures).

[132] Exec. Order No. 12898.

[133] EPA, Residual Risk Report to Congress, EPA-453/R-99-001 at 42, 67 (Mar. 1999) (discussing factor of "overall health" and recognizing the need to consider sensitive subpopulations that "consist of a specific set of individuals who are particularly susceptible to adverse health effects because of physiological (e.g., age, gender, pre-existing conditions), socioeconomic (e.g., nutrition), or demographic variables, or significantly greater levels of exposure," based on various demographic factors).

[134] EPA, *National Air Toxics Program: The Second Integrated Urban Air Toxics Report to Congress* at xiv (Aug. 21, 2014), https://www.epa.gov/sites/production/files/2014-08/documents/082114-urban-air-toxics-report-congress.pdf.

not fully evaluated the risks as required by § 7412(f)(2). And it is arbitrary because EPA can have no rational basis for ignoring this information, or the fact that it shows additional risk beyond that estimated by EPA here.

As the NAS discussed, "EPA should compile relevant data related to socioeconomic status (SES), which may serve as a proxy for numerous individual risk factors … and may be a more direct measure of vulnerability than could reasonably be assembled by looking at all relevant individual risk factors."[135] EPA should follow the NAS recommendations and review and address these risk factors in this risk assessment.

In addition, or in the alternative, EPA should simply use a default factor to account for socioeconomic and other community-based stressors, just as it does to account for intrinsic biological factors.[136] For example, it traditionally uses a factor of 100 to account for the use of animal studies, when translating such studies to assess human impacts. The Food Quality Protection Act directed EPA to use a factor of at least 10 to account for *in utero* exposure. California's OEHHA uses a similar factor to account for *in utero* exposure. EPA also uses age-dependent adjustment factors in other contexts. EPA should do the same to account for increased vulnerability based on socioeconomic factors or the presence of multiple sources to which a community is exposed.

4. EPA underestimates acute health risks.

EPA found that the maximum acute risk could be has high as 42, 33, 15, and 4, at some facilities – and is above 1 at all of them. *See* Acute Risk Modeling Memo at 2 tbl. 7, https://www.regulations.gov/EPA-HQ-OAR-2018-0417-0021; HCl RRA App. 10 at 1 tbl. 4 (Detailed Risk Modeling Results). EPA then stated that it "refined" the analysis, and determined that refined values were all under 1, and no higher than 0.7.

The documentation EPA provides on acute risk is unexplained and internally contradictory. EPA provides maps that include a range of values, without showing where facility boundaries are. *See, e.g.*, *id.*; HCl RRA App. 10 (Detailed Risk Modeling Results). EPA's two main tables include different numbers for the "original acute HQ" or "HEM-3 (screening)" values. The ultimate "off-site acute hazard quotient" is above 1 for at least two facilities in Table 7 (Refined Acute Modeling Results), at 2 and 4; but is presented as below 1 for those facilities in Table 4.

EPA has failed to rationally support its acute risk estimates, or to explain why the peak value – the highest of which is 42 times EPA's HQ threshold of 1 – is not the best available data showing the likelihood for acute harm. EPA has not provided any reasoned explanation for using 0.7 as the value it is focusing on for the risk acceptability determination.

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[135] NAS 2009 at 226 (citing O'Neill et al. (2003)).

[136] Morello-Frosch R., et al., *Understanding The Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*, 30(5) Health Affairs 879, 881 nn.24-26 (2011) (citing sources).

Further, EPA's acute risk assessment also irrationally ignores non-routine, malfunction or upset-based emission spikes and is therefore also incomplete, an underestimate, and unlawful and arbitrary for reasons discussed in Part IV.A.2.

EPA's failure to provide information that allows the public to understand and meaningfully comment on the acute risk information is also a violation of notice-and-comment under the Act. *See* 42 U.S.C. § 7607(d)(3)-(6), (h).

EPA also presents information using emergency-based values that have no place in a public health risk assessment of this kind. EPA looks at inappropriate values (i.e., the AEGLs and ERPGs), which are designed only for emergency exposure response and cannot be considered health-protective for community members facing potentially repeat exposures over a lifetime to acute risks from emission spikes.[137] EPA is underestimating acute risks by using those values.

Furthermore, in the course of determining acute risk, EPA estimated the peak emissions from the regulated units that it would use to assess this threat. EPA chose to base its assumption of peak emissions on estimates, and uses a factor of 10 to estimate acute health risks. However, among other things, the ratio of mean to peak emissions will vary depending on whether the emissions from the sources are controlled by a pollution control device and whether the processes involved are continuous or batch processes. EPA provides no detailed evaluation of the data or any explanation of how its multiplier is the most accurate estimate, or how likely it is that emissions are not much higher during certain periods.

EPA's acute risk assessment requires further explanation and a new round of public notice-and-comment. EPA may not lawfully finalize its § 7412(f)(2) proposed determinations of acceptability and an ample margin without assuring that it has, and presents for public review a scientific assessment of acute risk that is supported based on best available science in the record.

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[137] The AEGL values (and Emergency Response Planning Guidelines ("ERPG") values, which EPA also should not use) were created for emergency exposure scenarios. Levels defined for "once-in-a-lifetime, short-term exposures" and "emergency planning" for "single exposures" to chemical releases or accidents, 84 Fed. Reg. at 1577, are not appropriate tools to use to measure the acceptability of acute risks over a lifetime from one or more potential exposures due to an industrial source's emissions. As SAB has explained:

> The incorporation of the available California Reference Exposure Levels (RELs) for the assessment of acute effects is a conservative and acceptable approach to characterize acute risks…. The Panel has some concern with the use of the Acute Exposure Guidelines Limits (AEGLs) and Emergency Response Planning Guidelines (ERPGs)…. AEGL-2 and ERPG-2 values should never be used in residual risk assessments because they represent levels that if exceeded could cause serious or irreversible health effects.

SAB May 2010 at 6. The AEGL and ERPG numbers would be expected to underestimate risk. Using these numbers is likely to discount or cloak the level of risk to the maximum exposed individual. These values are therefore not appropriate for rely on as health-protective in a section 7412(f)(2) residual risk analysis. They simply do not provide sufficient protection for health.

5. EPA unlawfully and arbitrarily performs no multipathway risk assessment.

EPA is legally required to perform a multipathway (i.e., non-inhalation-based) risk assessment as part of this rulemaking, in addition to assessing inhalation risks. EPA's assessment here is incomplete, unlawful, and arbitrary in the ways detailed below. The net result is a significant underestimate of health risks from these facilities and therefore, flawed decision-making in EPA's proposed decision not to set residual risk standards for these facilities.

EPA performed no multipathway risk assessment because it proposes to find that no persistent bioaccumulative toxicants ("PBTs") are emitted. However, EPA must yet did not do this for the facility-wide risk assessment, even if no PBTs are emitted by HCl sources in particular.

As a result of not completing the multipathway risk assessment at least for the facility-wide emissions, EPA did not come up with a multipathway risk value for cancer or chronic non-cancer risk at all. So affected communities do not have information they need to evaluate that value, or the total.

EPA has found that the source category emits no persistent bioaccumulative toxicants, and so has determined not to perform a multipathway risk assessment. Commenters observe that this is yet another way in which EPA has underestimated health risk for the most-exposed individual. That is because EPA recognized high cancer risk due to inhalation, from HCl facilities, and significant chronic non-cancer risk from HCl sources and facilities, but did not assess any of the multipathway impacts of any pollutants for the collocated facilities. EPA should do so, as discussed in the Cumulative Risk Assessment comments and Appendix, to provide a more accurate real-world assessment of the true health risks to the most-exposed person.

C. EPA must assess the combined impact of multiple pollutants.

1. Assess the combined total of each type of risk for multiple pollutants, not just some risks.

In performing a cumulative risk assessment, the NAS suggests the consideration of chemical and non-chemical stressors as well as how these stressors work in concert to promote adverse health outcomes.[138] In this risk assessment, EPA recognizes that it must assess the combined impact of cancer risks from different carcinogens to create a combined cancer risk from inhalation and that it must assess the combined chronic non-cancer risk for different chemicals that affect the same target organ. This assessment is essential, and consistent with existing science. However, EPA should apply the same scientific principles to recognize that it also must combine and look at the whole picture of all other kinds of risk from multiple pollutants.

EPA fails to reach a combined cancer risk value that includes inhalation and multipathway risks of cancer, and that is unlawful and arbitrary. EPA must account for the aggregate impact of

[138] NAS 2009 at 9-10, 219-23.

inhalation and multipathway cancer and chronic non-cancer risk by adding each type of similar risk together for all pollutants.

The purpose of the multipathway assessment is to allow EPA to look overall at a person's exposure – not just inhalation, and not just other exposure pathways, in isolation. To do so, EPA must add inhalation and multipathway risk. Failing to add up each type of risk in order to come up with a *total* cancer risk number and a *total* non-cancer number, and then (as further discussed below), a *cumulative* burden metric makes EPA's overall risk assessment incomplete. In particular, EPA must assess the total and synergistic chronic noncancer risk for different pollutants that may work in different ways than EPA has acknowledged here.

Second, EPA also fails to assess an accurate chronic non-cancer risk total – because it looks only at a target organ or target organ system. EPA has focused on each individual "TOSHI," not a combined TOSHI. EPA has not added the TOSHI's even for inhalation. EPA recognizes that for the noncancer risk, some TOSHI values may be underestimated (HCl RRA at 32). The TOSHI largely underestimates risk by calculating the hazard index based on risk driven by a specific organ system as opposed to aggregating risk across all organ systems. The human body does not distinguish risk based on the highest risk driver to a particular organ system – risk is distributed across organ systems with pollutants affecting multiple organs or organ systems at once. EPA should aggregate or combine TOSHI values to account for total risk to chemical mixtures.

EPA has not assessed at all the chronic health risk that occurs for an individual experiencing multiple high TOSHI exposure simultaneously. Thus, the chronic risk is also sliced too narrowly and EPA should evaluate what it means for the person most exposed to HCl facilities who is facing respiratory harm plus liver, kidney, developmental, reproductive, and immunological harm, as EPA recognized all have high TOSHI values due to facility-wide risk.

Finally, EPA should apply these same principles to create a mechanism for assessing the total acute risk to chemical mixtures, at least in the way it is creating the TOSHI for chronic risk, that aggregates the acute impacts on the same organ systems for all pollutants. EPA's decision to assess acute risks solely chemical by chemical, when it knows the collection of HAPs is being released together, is unlawful and arbitrary. The result is an underestimation of the full acute health risks to which the most-exposed individual and nearby community members are exposed.

2. Assess the total cumulative risk burden from all pollutants.

EPA must create a metric to assess the total and cumulative risk burden, rather than only looking at each type of risk in a discrete, separate way.[139] EPA should be integrating its assessments and performing a "comprehensive risk assessment" as the NAS has emphasized.[140]

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[139] *See, e.g.*, NAS 2009 at 177 ("The underlying scientific and risk-management considerations point to the need for unification of cancer and noncancer approaches in which chemicals are put into a common analytic framework regardless of type of outcome.").
[140] *Id.* at 131; *see also id.* at 132-33 (discussing related issues).

After first assessing the total cancer, chronic non-cancer, and acute risks, for both inhalation and multipathway exposure, EPA also must create a metric to assess the total bundle of risks.[141] EPA must aggregate health risk for each pollutant, and each type of health risk, to create a cumulative risk determination for the individual "most exposed" to emissions as the Act requires.[142]

Unless and until EPA creates a combined health risk metric, it is unclear how it can make an ample margin of safety determination that is based on the full picture of health risk for a source category and that can be compared to other source categories. EPA must assess the full cumulative burden for public health. By failing to perform a full, cumulative risk assessment, EPA fails to gather the information needed to assess whether the risk to public health is acceptable under CAA § 7412(f)(2).

D. EPA must account for and quantify health risks from multiple sources.

EPA must assess and account for the cumulative impact and risk caused by exposure to multiple source categories' toxic air emissions – beyond the facility-wide risk – yet EPA has not evaluated any risks the most exposed person faces that come from sources beyond the facility's boundaries.

Such exposures increase the vulnerability of a community to new and additional toxic air emissions, as discussed above.[143] Further, EPA's own analysis recognizes that these sources create disproportionate health risk for minority and lower income communities. This problem is exacerbated even more by the fact that multiple toxic air sources are concentrated in minority and lower income communities, creating a serious environmental justice problem.[144] It is not enough for EPA to simply purport that it lacks the ability to assess health risks from multiple sources. In fact, EPA fails to assess these risks not because it is scientifically impossible, but because it feels the uncertainties from combining estimates from multiple source categories may make the assessment "unreliable." The potential uncertainty does not absolve the EPA of its duty to fully account for health risks for communities living near these facilities.

Therefore, in addition to performing a cumulative assessment from nearby sources in the same category, EPA also must perform a cumulative analysis that considers source categories' individual impact and risk with that of other sources to which people are exposed.[145] EPA has

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[141] CalEPA, Cumulative Impacts at 19-21, 25 (describing total "pollution burden" as sum of exposures, public health effects, and environmental effects); EPA, *Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document*, EPA/600/R-06/013F at 4-42 to 4-46 (Aug. 2007), http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=474337.

[142] 42 U.S.C. § 7412(f)(2).

[143] *See, e.g.*, NAS 2009 at 214.

[144] *See, e.g.*, CalEPA, Cumulative Impacts.

[145] We support EPA's recognition of the need to assess whether the maximum exposed individual is exposed to emissions from more than one source *within* each source category. We also appreciate that EPA has considered facility-wide risk in some way in this rulemaking. However, those assessments offer only part of the picture. And, even on both of these issues, EPA has provided very little information about what

acknowledged the importance of addressing multiple source exposures, by stating: "we are interested in placing source category and facility-wide HAP risk in the context of total HAP risk from all sources combined in the vicinity of each source," but refusing to do so because of "uncertainties." 84 Fed. Reg. at 1575. EPA has also recognized this need in its recent risk report.[146] Yet, so far EPA has failed to follow through on this. EPA goes on to call into question the reliability of conducting aggregate or cumulative assessments in light of key uncertainties, yet EPA never acknowledges that this means the entire assessment fails to provide an ample margin of safety.

Although EPA has assessed risk based on exposure to nearby existing sources within the source category, it has not proposed any changes to the emission standards based on the combined exposure with any other sources.

EPA has calculated what it calls "facility-wide" risk for different sources collocated at the same address, but it has not used that number to set standards which is unlawful and arbitrary (as discussed in Part I and II, above), and it has ignored other types of potential sources across the street or in close proximity. EPA should acknowledge that the multiple-source exposure risk, and the increased combined risk it creates through exposing people to multiple sources, require action.

In addition, EPA has provided no information at all on how it reached the "facility-wide" risk numbers. For example, EPA does not provide any detail on the emissions or risk estimates from particular sources it considered as collocated. It just provides the numbers in the record, without any way for the public to evaluate or comment meaningfully. This is a violation of the Clean Air Act's notice-and-comment requirements. 42 U.S.C. § 7607(d)(2)-(6), (9).

EPA's failure to assess the combined, cumulative impact on health risk from multiple pollution source categories conflicts with SAB's recommendation that EPA incorporate cumulative risk into its residual risk analysis. The SAB stated that "RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area."[147]

To perform a cumulative risk or impact analysis, EPA should combine current baseline emissions, exposures, and health impacts in addition to those of the specific source category EPA is reviewing. The NAS explained the need for "[i]ncorporation of background additivity to account for … [a]dditional sources of exposure to the same chemical or to similarly acting chemicals (including endogenous sources)… ."[148] As part of this analysis, EPA should aggregate

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it included in such assessments, as discussed elsewhere in these comments. EPA just states numbers found for facility-wide risk, without explaining where those numbers came from, how they were calculated, or what emission sources they cover. Most problematic, EPA refuses to take any regulatory action based on the unacceptable facility-wide risks it found.

[146] EPA, *Concepts, Methods and Data Sources* at xxxii (defining a cumulative risk assessment as including "aggregate exposures by multiple pathways, media and routes over time, plus combined exposures to multiple contaminants from multiple sources").

[147] SAB May 2010 at ii, 10.

[148] NAS 2009 at 180 (explaining that this may require the use of default factors).

or add the emissions for the most-exposed communities coming from: (1) the source category (including all individual sources within it); (2) facility-wide risk from collocated sources outside of this category; and (3) all other sources of toxic air pollution in the area. Virtually all of the existing federal air toxics standards (under section 7412(d)) require periodic testing and monitoring, and this is something EPA must ensure is included in all rules as it updates them. Using this data, EPA can aggregate the community's exposure and assess the full health threats faced by the affected community, including from the source under review.

Moreover, toxicology assessments typically ignore the impact of toxic exposures to genetics and epigenetics and the evidence that many adverse health impacts from environmental exposures, like chemicals in air pollution, can in fact be passed on to subsequent generations. This scientific evidence illustrates an additional dimension of the long-term harm that can occur in communities that have been and continue to be exposed to toxic air pollution over time.[149]

At a minimum, EPA can and should use the risk assessment results available for those source categories for which it has already performed a risk assessment review. Commenters recognize that other past risk assessments were also flawed and incomplete, but using and updating them as needed would be far better than ignoring the combined-source risks, and thus treating additional health risks people are facing as if it is not present. If EPA were to look at the combined risk results for these sources near one another (not just collocated) it would likely have to recognize that the overall risk is much higher than it has estimated for the most-exposed person near a source, such that stronger standards are needed under § 7412(f)(2) for these sources.

EPA must also consider the research that has already been published to assess health risk from toxic air pollution in urban communities nationwide.[150] EPA should draw on the OEHHA cumulative assessment approach.[151] EPA should consult with OEHHA and investigate the scientific approach it is using to address cumulative impacts, and consider and apply a similar science-based approach in this residual risk assessment.

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[149] *See, e.g.*, Bruner-Tran, KL, et al., *Developmental exposure to TCDD reduces fertility and negatively affects pregnancy outcomes across multiple generations*, 31 Reproductive Toxicology 344; Baccarelli A. *Breathe deeply into your genes: genetic variants and air pollution effects*, 179 American Journal of Respiratory and Critical Care Medicine 431 (Mar. 15, 2009); Rubes J., et al., *Genetic polymorphisms influence the susceptibility of men to sperm DNA damage associated with exposure to air pollution*, 683 Mutation Research 9 (Jan. 2010); Rubes J., et al., *Episodic air pollution is associated with increased DNA fragmentation in human sperm without other changes in semen quality*, 20 Human Reproduction 2776 (June 24, 2005); Sánchez-Guerra M., et al., *Environmental polycyclic aromatic hydrocarbon (PAH) exposure and DNA damage in Mexican children*, 742 Mutation Research 66 (Feb. 18, 2012).

[150] *See, e.g.*, Morello-Frosch, R., et al., *Separate and Unequal: Residential Segregation and Estimated Cancer Risks Associated with Ambient Air Toxics in U.S. Metropolitan Areas*, 114(3) Envtl. Health Persp. 386 (2006) (assessing toxic air pollution cancer risk for 309 metropolitan areas encompassing 45,710 tracts); National Air Toxics Program: The Integrated Urban Strategy, 64 Fed. Reg. 38,706, 38,738/1-2 (July 19, 1999).

[151] *See, e.g.*, CalEPA, Cumulative Impacts.

Further, the NAS has recommended that EPA evaluate "background exposures and vulnerability factors," as well as use "epidemiologic and toxicologic evidence" in its risk assessments.[152] Rather than separating an environmental justice analysis and considerations of inequality from the risk assessment, considering these factors as part of the cumulative risk assessment – because of the increased vulnerability created (as also discussed in Part I.E above) – would be a more effective, meaningful, and scientific approach.

In assessing a source category's emission contributions in affected communities and considering whether these contributions cause the most-exposed people to experience an unacceptable level of public health risk when combined with the existing baseline from past emissions, other HAP emissions, and the community's health status, EPA can describe and manage uncertainties, as it does and other federal agencies do for many other analyses.[153] Uncertainties do not justify failing to assess and address the severe cumulative harm and risk to local communities from air toxics sources. There is no excuse for treating an unknown amount of additional risk as a missing default, to use the NAS term.

As a scientific and policy matter, where there is exposure to air toxic emissions beyond the individual source category, the level of total risk that is occurring, including the baseline health risk and the risk from other sources, is greater. Thus, the total risk that is unacceptable for the most-exposed person must in fact be lower for each source category that person is exposed to, because it combines with other risks to create a *total* risk from all regulated source categories, which must be minimized. Looking at a source category's contribution of risk in isolation is equivalent to ignoring the facts and pretending other health risks are not occurring. EPA may not decide that it is acceptable for a person to be exposed at a higher level simply because they live in a community where they are exposed to multiple sources of air pollution. That is the opposite of what EPA is required to do – protect the people in local communities who are most exposed and most vulnerable to air pollution. It also conflicts with EPA's own commitment to consider and provide environmental justice to overburdened communities.

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[152] NAS 2009 at 221-23 (discussing Menzie et al. 2007 model); *id.* at 230 (discussing the role of epidemiology and surveillance data).

[153] *See, e.g.*, 42 U.S.C. §§ 7475(a)(3), 7503(a)(1) (requiring a localized, cumulative assessment of whether or not a new or modified source's additional emissions will cause an attainment area to deteriorate, or will make it difficult for a nonattainment area to make progress toward achieving the national ambient air quality standards); *New York v. EPA*, 443 F.3d 880, 883 n.1 (D.C. Cir. 2006) (citing *New York v. EPA*, 413 F.3d 3, 11-14 (D.C. Cir. 2005)); *see also* 40 C.F.R. § 1508.27(b)(7) (requiring a consideration of "[w]hether the action is related to other actions with individually insignificant but cumulatively significant impacts. Significance exists if it is reasonable to anticipate a cumulatively significant impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts"); *see also* 40 C.F.R. § 1508.7; *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 930 (9th Cir. 2008) (applying 16 U.S.C. § 1536(a)(2) to enforce the Endangered Species Act duty to ensure against jeopardy which includes the requirement to assess a newly proposed action in the context of all other impacts, and determine whether or not the specific action will "tip a species from a state of precarious survival into a state of likely extinction," or, where baseline conditions already jeopardize a species, whether it will "deepen[] the jeopardy by causing additional harm").

At a minimum, until EPA develops a data-driven approach to comprehensively model cumulative risk or impacts from multiple sources, EPA must not treat multiple source exposure as a missing default, or ignored amount of health risk. EPA must incorporate an explicit default or uncertainty factor to adjust the degree to which each individual source category is contributing to the total risk experienced by the most-exposed individuals. For example, wherever there is evidence that the source category is contributing pollutants on top of a history of other exposures or is contributing pollutants in addition to other source categories, the "unacceptable" level of cancer, noncancer chronic, and acute risk from the source category must be adjusted downward based on the number of other facilities contributing HAP exposure risks (such that no single source category could consume all of it, when the most-exposed person is exposed to many other source categories). For a source category in an area with up to 10 other HAP-emitting facilities, this default or uncertainty factor should equal at least 10, consistent with the common scientific use of this factor for other kinds of vulnerability.[154]

V. EPA Must Strengthen the Emission Standards to Comply with the Act's Requirements Pursuant to § 7412(d).

Clean Air Act § 7412(d)(6) requires EPA to review emission standards every eight years and revise them, as necessary, to account for developments in practices, processes, and pollution control technologies.[155] Its objective is to continue to strengthen the standards and thus reduce toxic air pollution, and Americans' exposure to air toxics, as greater emission reductions become achievable. Congress intended to ensure that limits on toxic pollution are not frozen at the levels achievable by technologies or practices the first time standards were set, and that subsequently become outdated.[156] This obligation is in addition to and independent from § 7412(f)(2). As EPA has recognized, § 7412(d)(6) is "a continuation of the technology-based section 112(d) standard-setting process," and it thus serves the same goals of 42 U.S.C. § 7412(d) overall to assure emission reductions.[157] EPA may determine that it is "necessary" to update the standards based on any relevant factors, but when such "developments" exist, it must update the standards, as developments are the "core requirement" of § 7412(d)(6).[158] In addition, EPA must update the standards when it is "necessary" to do so to satisfy § 7412 for reasons other than developments,

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[154] For areas with more facilities, which cause an even greater level of health risk combined, the uncertainty factor ("UF") should be adjusted accordingly, i.e., 11-20 facilities would result in an UF of 20, and more than 20 would result in an UF of 100, so the source category's contribution is no higher than 1/100 of the threshold.

[155] 42 U.S.C. § 7412(d)(6).

[156] *See* Hon. Henry Waxman, *An Overview of the Clean Air Act Amendments of 1990*, 21 Envtl. L. 1721, 1775-76 & n.256 (1991) (explaining that by including § 7412(d)(6), Congress intended that "the continual tightening of existing source standards will be assured").

[157] *See, e.g.*, Subpart N: Summary of Public Comments on Chromium Electroplating and Steel Pickling Risk and Technology Review (RTR), EPA-HQ-OAR-2010-0600-0691, at 3 (Aug. 15, 2012), https://www.regulations.gov/document?D=EPA-HQ-OAR-2010-0600-0691; 42 U.S.C. § 7412(d)(2)-(3); S. Rep. No. 101-228 at 127-33, *reprinted in* 1990 U.S.C.C.A.N. at 3512-18.

[158] *NRDC v. EPA*, 529 F.3d at 1084.

such as because the existing emission standards do not comply with relevant requirements of § 7412 as shown by intervening legal precedent.

As part of its review rulemaking under § 7412(d)(6) of existing standards to determine whether it is "necessary" to revise the standards, EPA must ensure that standards for HCl facilities meet the requirements of § 7412(d), consistent with its responsibility under the Act and applicable case law.[159] Therefore, as a result of prior similar reviews, EPA has recognized the need to set limits on previously unregulated pollutants, previously unregulated emission points, and has corrected other problems with emission standards to ensure standards are in place that comply with the Act.[160] Although EPA has authority to review and strengthen emission standards to ensure that the agency satisfies the Act at any time, the § 7412(d)(6) review rulemaking is a time when the law requires EPA to do so.[161] The Act requires that EPA "shall" take required § 7412(d)(6) rulemaking action "no less often than *every* 8 years." 42 U.S.C. § 7412(d)(6) (emphasis added).

A. EPA must remove the unlawful exemptions in the standards, for startup, shutdown, and malfunction ("SSM") periods, as it proposes to do, as well as the exemption for 240 hours per year during "maintenance."

Commenters support EPA's proposed removal of the exemption in the regulations for emissions during startup, shutdown and malfunction periods. 84 Fed. Reg. at 1584-85. EPA may not retain this exemption because it is unlawful and arbitrary, due to the Act's requirements that

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[159] *See, e.g.*, 84 Fed. Reg. at 1584 ("We are proposing revisions to the malfunction provisions of the MACT rule in order to ensure that they are consistent with the Court decision in *Sierra Club v. EPA*, 551 F. 3d 1019 (D.C. Cir. 2008)").

[160] *See, e.g*, Wool Fiberglass Final Rule, 80 Fed. Reg. 45,280, 45,310-11 (July 29,2015) (explaining that the agency was changing the existing standards in part to assure that they satisfy § 7412(d)(2)-(3), consistent with the Act and D.C. Circuit caselaw, and stating that "[f]urther, CAA section 112(d)(6) itself provides that the agency must review and revise 'as necessary.' The 'as necessary' language must be read in the context of CAA section 112(d)(6), which focuses on the review of developments that have occurred since the time of the original promulgation of the MACT standard and, thus, can be used as an opportunity to correct flaws that existed at the time of the original promulgation."); Chromium Plating Final Rule, 77 Fed. Reg. 58,220, 58,238 (Sept. 19, 2012) ("EPA believes that the alternate source specific provision does not meet the requirements in section 112(d)(2) and (3) of the CAA, and the CAA does not allow the regulatory flexibility to set source-specific concentration standards for particular pollutants. We disagree to the extent the commenter is suggesting that because EPA previously promulgated the alternative, it therefore must be consistent with the CAA. Neither the proposed nor final MACT rule provided the legal basis for the alternative and, since that time, the courts have rejected similar provisions in other standards. (72 FR 61060)."; "[W]e are making this correction under CAA sections 112(d)(2) & (3) because we believe that the alternative compliance option was improperly promulgated at the time we promulgated the initial MACT standard").

[161] *See, e.g.*, *Portland Cement Ass'n v. EPA*, 665 F.3d 177, 189 (D.C. Cir. 2011) ("[t]hough EPA must review and revise standards 'no less often than every eight years,' 42 U.S.C. § 7412(d)(6), nothing prohibits EPA from reassessing its standards more often"); *see also Med. Waste Inst. & Energy Recovery Council v. EPA*, 645 F.3d 420, 425 (D.C. Cir. 2011) ("nothing in the Clean Air Act or in the *Sierra Club–HMIWI* decision suggests that [EPA] is prohibited from resetting the [maximum achievable control technology] floors in order to correct its own errors").

emission standards be continuous, and apply at all times. 42 U.S.C. §§ 7412, 7602(k). Repeatedly, the D.C. Circuit has so held and EPA has so recognized in prior rulemakings.[162] EPA must eliminate this exemption, as it has proposed to do, because removing this problem in the existing standards is "necessary" under § 7412(d)(6).

Although EPA appropriately does not propose any such attempt at a standard here, it still claims discretion "to set standards for malfunctions." 84 Fed. Reg. at 1585. EPA has not cited and can cite no statutory language granting it authority to set such standards, because it has none. Rather, EPA has only the discretion provided by the Act and delegated by Congress. *See, e.g.*, *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017). The relevant statutory language denies, rather than gives, EPA authority to set malfunction-based standards or exemptions. *See* 42 U.S.C. §§ 7412(d), (h), 7602(k). Community, environmental, and environmental justice groups petitioned the agency for administrative reconsideration, and filed a petition for review of the only such standard it has tried to create (in the Refinery Sector Rule the proposal cites).[163] Their reconsideration petition and comments filed in support of that petition and offered at the November 2016 public hearing have shown that the Refinery Rule malfunction exemption is unlawful and arbitrary and should be removed from the standards.[164] EPA still has not acted on their reconsideration petition. The D.C. Circuit has held the case in abeyance, waiting first to see if EPA corrects its own errors before reviewing the rule. As the malfunction exemption in that rule remains under a cloud of substantial controversy and is unlawful and arbitrary, it provides no support for any other similar proposal. EPA may not contravene core Clean Air Act requirements to assist industry sources that prefer not to take basic steps to reduce toxic air pollution, rather than rewarding industry leaders that do so and reach the lowest achievable limits.

EPA does not propose to remove the 240-hour per year exemption from emission limits "during periods of planned routine maintenance of HCl storage tank control devices." 40 C.F.R. § 63.9000. Because that is an unlawful exemption from the requirement that emission limits must be "continuous" and apply at all times, as discussed above, EPA must also remove that exemption

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[162] *See, e.g.*, *Sierra Club v. EPA*, 551 F.3d 1019, 2018 (D.C. Cir. 2008); NESHAP for Chemical Recovery Combustion Sources at Pulp Mills, 82 Fed. Reg. 47,328, 47,331 (Oct. 11, 2017); NESHAP for Yeast, 82 Fed. Reg. 48,156, 48,159 (Oct. 16, 2017).

[163] *Air Alliance Houston et al. v. EPA*, D.C. Cir. No. 16-1035 (filed Feb. 7, 2016) (held in abeyance pending EPA action on reconsideration).

[164] *See* Pet'n for Recon. filed by Air Alliance Houston, California Communities Against Toxics, Clean Air Council, Coalition For A Safe Environment, Community In-Power & Development Association, Del Amo Action Committee, Environmental Integrity Project, Louisiana Bucket Brigade, Sierra Club, Texas Environmental Justice Advocacy Services, and Utah Physicians for a Healthy Environment (Feb. 1, 2016), https://www.regulations.gov/document?D=EPA-HQ-OAR-2010-0682-0860; Tr. of EPA Public Hearing in Houston, TX (Nov. 17, 2016), https://www.regulations.gov/document?D=EPA-HQ-OAR-2010-0682-0933; Recon. Comments of Air Alliance Houston, California Communities Against Toxics, Clean Air Council, Coalition For A Safe Environment, Community In-Power & Development Association, Del Amo Action Committee, Environmental Integrity Project, Louisiana Bucket Brigade, Sierra Club, Texas Environmental Justice Advocacy Services, and Utah Physicians for a Healthy Environment (Dec. 19, 2016), https://www.regulations.gov/document?D=EPA-HQ-OAR-2010-0682-0889.

as another example of a source-specific SSM exemption. 42 U.S.C. § 7602(k); *Sierra Club v. EPA*, 551 F.3d at 1028.

EPA also does not propose to set hard limits on equipment leaks. It must do so as currently EPA's rules allow for unlimited emissions through leaks. The rules require only a "Leak Detection and Repair ("LDAR") plan" without any specific limits or requirements on the amount of HAPs that fugitive emissions or leaks can release into the atmosphere. There is no prohibition on such leaks and EPA should clearly add this into the rules as well. *See* 40 C.F.R. Subpart NNNN tbl. 1 (requiring the facility only to "[p]repare and operate at all times according to an equipment LDAR plan that describes in detail the measures that will be put in place to detect leaks and repair them in a timely fashion"), tbl. 5 (requiring just verification that the source "continue[s] to use a LDAR plan" and "[r]eporting any instances where [it] deviated from the plan and the corrective actions taken."). EPA must therefore remove the unlimited leak allowance as another type of SSM exemption.

B. EPA must not set a "maintenance vent" standard, for particular types of high emissions, as industry has requested.

Dow Chemical has requested that EPA create a new exemption – a special provision allowing it, and all other regulated facilities, to evade numerical emission limits during certain time periods. EPA is taking comment on Dow's proposal, and the "regulatory text it submitted"; EPA should reject Dow's proposed regulatory changes as unlawful and arbitrary. 84 Fed. Reg. at 1589 (citing Dow correspondence, EPA-HQ-OAR-2018-0417). There are multiple emails between EPA and Dow Chemical in the record, including communication where Dow is seeking a work practice standard instead of an emission limit; however, Commenters were unable to find any actual "regulatory text" that EPA is considering or proposing.

Dow Chemical's request for a "maintenance vent" standard is based solely on the fact that EPA must remove the current exemption in the standards for "startup, shutdown, and malfunction" periods. *Id.* It is not based on the fact that vents are affiliated with different equipment or any other differences that might justify a different standard. It appears to be for the purpose of avoiding the numerical emission limits. Dow proposes this as a work practice standard.

EPA may not set a work practice standard without meeting § 7412(h)(1)-(4) of the Act, which requires a determination that it is not feasible or practicable to measure or enforce a numerical limit. EPA cannot meet that test because it has already recognized the need to set numerical limits for these sources and has done so. EPA has found such standards can and should be set, and no data Dow has provided contradicts that. There is no evidence in the record that a facility cannot reduce operations or take other steps needed to avoid any violations or exceedances of the numerical standards during periods of maintenance. Allowing a facility to avoid taking necessary preventive measures, and instead allow unlimited amounts of HAPs to be released under the guise of "maintenance," would violate the Act and be arbitrary. This type of provision is vulnerable to abuse by a facility who may have a malfunction that then requires "maintenance," and attempt to avoid recognizing an exceedance of the numerical limit by labelling the release as through a "maintenance vent."

Further, to the extent there are pressure relief devices or other valves that Dow seeks to bring under a new "maintenance vent" requirement, EPA must make clear that uncontrolled releases of HAPs to the atmosphere are unlawful, and prohibit them as EPA has done in other chemical plants rules.[165] The Act does not allow any uncontrolled releases of HAPs from a major source, and EPA must ensure that there is a numerical limit that applies (which meets the test pursuant to § 7412(d)(2)-(3), and (f)(2)), or simply prohibit any such uncontrolled releases. There is no reason why a maintenance vent and/or valve cannot be vented to a control device, as EPA is well aware and has required in prior rules for similar sources. Setting what the Act requires provides an incentive to perform regular maintenance and take preventative steps needed to ensure all equipment is operating properly, and so there will not be the need for unanticipated, high releases of pollution for which the facility's control devices are not prepared or equipped.

EPA has not provided any proposed regulatory text or rationale of its own or reasoned explanation based on any data in the record for such a maintenance provision, and therefore it could not finalize one without providing notice and comment on such a rationale. 42 U.S.C. § 7607(d)(3)-(7), (h).

EPA may not set an exemption from the emission standards by trying to cloak this as a work practice standard. It would undermine and weaken the numerical emission standards to allow industry to label a vent "maintenance," and avoid the applicability of those numerical limits, during periods of time it chooses. This would also violate the Act's requirement that emission standards must be "continuous" and apply at all times. 42 U.S.C. § 7602(k); *Sierra Club v. EPA*, 551 F.3d 1028 (D.C. Cir. 2008). As EPA is well aware, the D.C. Circuit has recognized that EPA's attempt to create a new type of malfunction exemption in the guise of or labelled as something else is still unlawful. *See, e.g.*, *NRDC. v. EPA*, 749 F.3d 1055, 1063-64 (D.C. Cir. 2014) (finding affirmative defense to civil penalties due to malfunctions unlawful).

C. EPA Must Set Emission Standards and Complete a Technology Review for Wastewater Treatment at HCl Production Facilities.

It is well established that, under § 112(d) of the Clean Air Act, EPA must set emission standards for each hazardous air pollutant that a source category emits. 42 U.S.C. § 7412(d). As the D.C. Circuit held in *National Lime Ass'n*, 233 F.3d 625, 634 (D.C. Cir. 2000), the agency has a "clear statutory obligation to set emission standards for each listed HAP."

In subsequent decisions, the D.C. Circuit has repeatedly held that EPA has violated that obligation. *See, e.g.*, *Sierra Club v. EPA*, 479 F.3d 875, 883 (D.C. Cir. 2007). Despite the plain language of the Clean Air Act and D.C. Circuit precedent, the existing standards do not currently contain *any limit* at all on HAPs coming from wastewater systems.

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[165] EPA, NESHAP: Off-Site Waste & Recovery Operations; Final Rule, 80 Fed. Reg. 14,248, 14,275-76 (Mar. 18, 2015); EPA, NESHAP: Group IV Polymers & Resins; Pesticide Active Ingredient Production; and Polyether Polyols Prod., Final Rule, 79 Fed. Reg. 17,340, 17,344-45 (Mar. 27, 2014); EPA, NESHAP: Generic MACT; and Manuf. of Amino/Phenolic Resins, Final Rule, 79 Fed. Reg. 60,898, 60,905 (Oct. 8, 2014).

EPA has identified the emission points at these facilities as process vents, storage tanks, transfer operations, equipment leaks, *and wastewater*. 66 Fed. Reg. 48,174, 48,176 (Sept. 18, 2001). Although EPA set emission limitations or work practice standards for four of the five emission points, and has proposed to review and consider revising those here, it has failed to regulate and to review or revise the no-control standard for HAP emissions from wastewater. For both new and existing sources, originally EPA set the MACT floor for wastewater as "no emission reduction," claiming that it did not identify any add-on controls, process modifications, or other pollution-prevention measures currently in use to control HAP emissions from wastewater. 66 Fed. Reg. at 48,181.

In the proposed rule, EPA does not discuss, much less assess any health risks, or issue any determinations under § 7412(f)(2) or (d)(6), as required, for these emission points.

"No control" standards contravene EPA's "clear statutory obligation to set emission standards for each listed HAP." *National Lim*e*,* 233 F.3d at 634. EPA found that wastewater is part of the affected source at HCl production facilities. 68 Fed. Reg. 19,076, 19,079 (Apr. 17, 2003). Therefore, the Agency must review, and revise the standards as "necessary" under § 7412(d)(6) to set emission standards that satisfy § 7412(d)(2)-(3) for these emission points. EPA also must assess health risks caused by these uncontrolled HAP emissions, and assure the requisite "ample margin of safety to protect public health" from these emissions. 42 U.S.C. § 7412(f)(2). It fails to do either, and therefore its action is unlawful, incomplete, and arbitrary.

Binding D.C. Circuit precedent, starting with the 2000 decision in *National Lime* and continuing with later decisions, confirms EPA's "clear statutory obligation" to set emission standards for each listed hazardous air pollutant that HCl facilities emit. 233 F.3d at 633. Thus, it was clear since the time that the original standards were set in 2003 that EPA's failure was flatly unlawful, and that EPA's emission standards do not satisfy the Act. Nonetheless, EPA made no effort to correct the rule's legal defects or to provide exposed communities with the protection EPA knew the Clean Air Act required it to provide. Instead, EPA simply let its unlawful rule sit on the books for years.

While EPA has been ignoring its statutory obligations to control these sources' toxic pollution, people in communities near these sources suffered as a result of their exposure to uncontrolled inorganic HAP emissions. In January 2009, Sierra Club also submitted a petition for rulemaking to EPA, urging EPA to set the missing emission limits for HCl sources, and to follow § 7412(d)(2)-(3) requirements in doing so. *See* Pet'n of Natural Resources Defense Council & Sierra Club to Adm'r Stephen L. Johnson at 13 (Jan. 14, 2009) (attached) (discussing uncontrolled HAPs in this source category). To date, EPA has provided no formal response to that petition for this or any source category, demonstrating substantial unreasonable delay, as over ten years have now passed. Instead, in its § 7412(d)(6) rulemakings for particular source categories EPA has repeatedly set missing limits for source categories on a category-by-category basis, and in some instances, has noted that it is doing so in part to resolve part of that petition.[166]

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[166] *See, e.g.*, Primary Lead NESHAP, Final Rule, 76 Fed. Reg. 70,834 (Nov. 15, 2011) (explaining that the rule was in part responding to the 2009 petition and determining that, although EPA refused to recognize

Now, in this rulemaking, EPA is required to "review, and revise as necessary" the emission standards for HCl production sources. 42 U.S.C. § 7412(d)(6). EPA is blatantly ignoring this obligation in regard to the "no control" standards for wastewater. EPA neither acknowledges its statutory obligation to set limits on such uncontrolled HAPs, nor provides any justification for how it could refuse to find that it is "necessary" to revise the existing standards to set a limit.

Further, EPA has failed to complete a technology review of the current standards' treatment of the HAPs emitted by wastewater – *i.e.*, the no-control allowance for them. EPA cannot determine whether developments in pollution control make it "necessary" to revise the emission standards without first determining what developments, if any, have occurred for all HAPs emitted by HCl sources.

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this was required, that it was "reasonable" to "address a purported flaw in a promulgated standard" in the pending § 7412(d)(6) rulemaking). In this notice, EPA further stated that it was "reasonable to make corrections" in such a rulemaking, and has explained further that it has done this repeatedly:

> In several recent rulemakings, we have chosen to fix underlying defects in existing MACT standards under sections 112(d)(2) and (3), the provisions that directly govern the initial promulgation of MACT standards (see National Emission Standards for Hazardous Air Pollutants From Petroleum Refineries, October 28, 2009, 74 FR 55670; and National Emission Standards for Hazardous Air Pollutants: Group I Polymers and Resins; Marine Tank Vessel Loading Operations; Pharmaceuticals Production; and the Printing and Publishing Industry, April 21, 2011, 76 FR 22566).

Id. at 70,846; *see also, e.g.*, Generic MACT NESHAP, Final Rule, 79 Fed. Reg. 60,898 (Oct. 8, 2014) ("In addition, we are taking final action addressing emissions during periods of startup, shutdown and malfunction, and are adding standards for previously unregulated hazardous air pollutant (HAP) emissions sources for certain emission points. "); Polymers & Resins Group IV; Pesticide Active Ingredient Production; Polyether Polyols Prod. NESHAP, Final Rule, 79 Fed. Reg. 17,34017340, 17,340 (Mar. 27, 2014) ("This action finalizes the residual risk and technology review conducted for nine source categories regulated under the National Emission Standards for Hazardous Air Pollutant Emissions: Group IV Polymers and Resins; Pesticide Active Ingredient Production; and Polyether Polyols Production. Today's action promulgates amendments concerning the following: Residual risk reviews; technology reviews; emissions during periods of startup, shutdown and malfunction; standards for previously unregulated hazardous air pollutant emission sources"); Polymers & Resins I NESHAP, Final Rule, 76 Fed. Reg. 22,566, 22,569 (Apr. 21, 2011) ("establishing standards at the MACT Floor level of control for previously unregulated . . . HCl emissions..."); Oil and Gas NESHAP, 77 Fed. Reg. 49,490, 49,490, 49,492, 49,530 (Aug. 16, 2012) ("In addition, the EPA has established in this action emission limits reflecting maximum achievable control technology for certain currently uncontrolled emission sources in these source categories."; "This rule establishes MACT standards for major sources of small glycol dehydrators that were left unregulated in the 1999 MACT rule. As explained further below, in several recent rulemakings, we have chosen to fix certain underlying defects in existing MACT standards under CAA sections 112(d)(2) and (3), which are the provisions that directly govern the initial promulgation of MACT standards (see National Emission Standards for Hazardous Air Pollutants From Petroleum Refineries, October 28, 2009, 74 FR 55670; and National Emission Standards for Hazardous Air Pollutants: Group I Polymers and Resins; Marine Tank Vessel Loading Operations; Pharmaceuticals Production; and the Printing and Publishing Industry, April 21, 2011, 76 FR 22566). We believe that this approach is reasonable because using those provisions ensures that the process and considerations are those associated with initially establishing a MACT standard, and it is reasonable to make corrections following the process that would have been followed if we had not made an error at the time of the original promulgation.").

EPA also failed to include any emitted HAPs from these emission points in its risk assessment. There is no discussion of wastewater emissions at all in the Risk Assessment, which only lists other emission points. *See* HCl RRA at 5. EPA assumed health risks are zero from these emissions, but cannot support this with any evidence, much less substantial evidence or a reasoned explanation based on it. Refusing to assess these emissions from the HCl source category violates § 7412(f)(2) and makes the risk assessment unlawfully and arbitrarily incomplete. EPA's proposed risk acceptability and ample margin determinations are thus also unlawful and irrational because they are based on incomplete information.

That HAPs are present as emissions from any source in the category is sufficient to require EPA to evaluate them pursuant to the technology review and risk assessment and determination. EPA has emissions data from at least some sources and it must complete its obligation to set a limit for these HAPs, and to perform a technology and health risk assessment regulatory review to determine ways to reduce them beyond the current no-control standard.

As communities currently have no protection at all from these emitted HAPs, it is both unlawful and arbitrary for EPA not to set a limit in this rulemaking. If it fails to do so, it will fail to complete the review and revision rulemaking as § 7412(d)(6) requires, in contempt of the Court's Order in *California Communities Against Toxics v. Pruitt*, 241 F. Supp. 3d 199 (2017), and will also issue a final rule that is unlawful and inadequate.

D. EPA Must Fulfill Its Obligation to Complete a Technology Review that Accounts for all "Developments" and Assures that EPA Revises the Existing Emission Standards "As Necessary."

EPA proposes not to revise the emission standards for HCl production at all due to what it describes as a lack of "developments" under § 7412(d)(6). EPA states in the notice of proposed rulemaking that it has based this proposed determination on the required technology review, and describes "the results" of that review, data and information it says it reviewed, but it presents none of this evidence in the record.

In this type of rule EPA has a longstanding policy of creating and presenting a Memorandum that describes the sources EPA reviewed and the results of that review. However, the record does not appear to contain this. Failing to include this information is a violation of notice-and-comment under 42 U.S.C. § 7607(d)(3)-(7), (h).

EPA must place into the public docket all information it relied on to allow for meaningful public comment and court review. EPA cites and states that it is relying on "clearinghouse" information, Title V permits, information on "scrubbers," and information described as the "results" of the technology review. 84 Fed. Reg. at 1584. Yet none of this information is in the record for public review.

EPA has the burden to support its proposed rule with substantial evidence and a reasoned explanation, under the Act. 42 U.S.C. § 7607(d)(9).

Failing to present any of the underlying information EPA relied on for its § 7412(d)(6) determination makes it impossible for the public and for a reviewing court to evaluate EPA's conclusory determination that there are "no developments" requiring revision.

Furthermore, EPA should consult with states and local air districts, and with the Institute of Clean Air Companies, and request information from pollution control and monitoring companies regarding developments in controls for the pollutants at issue in this rulemaking. This information should be readily available to EPA, as it is to companies or other entities who may wish to purchase or use those technologies. EPA's technology review could not be complete without assuring EPA has the best available information on current controls, from the actual pollution control manufacturers and distributors. Failing to go directly to the source of such controls biases EPA's technology review away from the most current developments. It would be arbitrary and capricious for EPA not to assess the technologies and tools available in the market for the control of the pollutants at issue here and provide this information for notice-and-comment. Providing information on these tools has a strong positive value for the regulated industry as well as community members exposed to pollution. This information may lead some regulated sources to implement tools about which they currently have no information, which would create jobs and increase the economic success both of the regulated facility and the company providing the control or monitoring tools.

Substantively, contrary to EPA's proposed conclusion, Commenters believe that there *are* developments in VOC and acid gas controls, leak detection and repair, and monitoring that EPA must consider and ensure that the standards "tak[e] into account" for this source category and HCl facilities. Commenters do not have access to the range of information EPA has, and that is partly why it is so prejudicial that EPA has not provided the information it used (and cited) for its technology review. However, since EPA finalized the original standards, EPA has recognized such developments in other contexts, and Commenters provide information on developments of which they are aware.

In addition to scrubbers which EPA says are already used, there is a development available for control of acid gases that EPA must "take into account" under § 7412(d)(6): dry sorbent injection, with fabric filters or electrostatic precipitators.[167] As EPA has found:

> A DSI system is used to inject powdered alkaline sorbent (typically sodium- or calcium-based sorbents) into the flue gas stream. The alkaline sorbents neutralize acidic gases and the resulting solids are captured in a downstream PM control device (*e.g.*, a fabric filter). DSI has been identified as a relatively low-cost technology for control of acid gases.[168]

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[167] Institute of Clean Air Companies ("ICAC"),, *Dry Sorbent Injection for Acid Gas Control: Process Chemistry, Waste Disposal and Plant Operational Impacts* (July 2016), https://cdn.ymaws.com/www.icac.com/resource/resmgr/white_papers/ICAC_Industrial_DSI_Ancillar.pdf.

[168] EPA, NESHAP: Coal- and Oil-Fired Electric Utility Steam Generating Units – Reconsideration of Supplemental Finding and Residual Risk and Technology ReviewRecon, Proposed Rule, 84 Fed. Reg. 2670, 2702 (Feb. 7, 2019).

EPA has also identified spray dryer absorbers ("SBA") as an additional type of control for HCl.[169] EPA must evaluate these controls as "developments," that could strengthen emission reductions of the acid gases emitted here – HCl and Cl.

In addition, there are also developments in monitoring of acid gases – particularly HCl. As ICAC has highlighted, EPA has required monitoring of HCl in multiple national standards in recent years. EPA should strengthen monitoring here due to these demonstrated developments.[170]

EPA must also account for developments in addressing and reducing equipment leaks, using the most up-to-date leak detection and repair methods. Currently the rules just require a non-specified "LDAR plan," without any hard limit or specific requirements of any kind to prevent or reduce equipment leaks, or corrective action required within any specific timeframe. *See* 40 C.F.R. Subpart NNNN tbl. 1 (requiring the facility only to "[p]repare and operate at all times according to an equipment LDAR plan that describes in detail the measures that will be put in place to detect leaks and repair them in a timely fashion"), tbl. 5 (requiring just verification that the source "continue[s] to use a LDAR plan" and "[r]eporting any instances where [it] deviated from the plan and the corrective actions taken.").

EPA has current LDAR developments information but has not reviewed any of it for this rulemaking. For example, using low-emission valves, and optical gas imaging can increase the effectiveness of leak monitoring and ensure faster repair.[171] Additional deployment of infrared ("IR") or open-path FTIR systems can supplement other monitoring. In addition, EPA should take information from enforcement of existing LDAR programs and use that to strengthen the regulations.[172] For example, EPA should "take into account" the following LDAR developments from its own consent decrees:

- Lowering the leak definition, to capture leaks at lower and still potentially harmful levels, such as 250 ppmv or lower;
- Requiring "low-leak" technology and other materials for repairs;
- Periodic monitoring of devices used for closure of open-ended lines;

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[169] *Id.*
[170] ICAC, *White Paper: Monitoring of HCl* (2013), https://cdn.ymaws.com/www.icac.com/resource/resmgr/standards_whitepapers/hci_whitepaper_final_030113.pdf.
[171] Drago, J., "LDAR Programs Continue to Evolve," Envtl. Protection (Aug. 24, 2016), https://eponline.com/Articles/2016/08/24/LDAR-Programs-Continue-to-Evolve.aspx?admgarea=Features&m=1&Page=3&p=1.
[172] EPA, Office of Enforcement and Compliance Assurance, (Oct. 2007), https://www.epa.gov/compliance/leak-detection-and-repair-best-practices-guide; Air and Waste Management Ass'n ("AMWA"), EPA Priority: Leak Detection and Repair (LDAR) (2014), http://pubs.awma.org/flip/EM-Nov-2014/darrat.pdf.

- Requiring more stringent or faster repair when leaks are found, which will reduce the amount of HAPs allowed to leak into the air;

- Require monitoring audits using third parties for leak-prone equipment, closure devices, valves, pumps, connectors, agitators, etc.;

- Require more frequent regular monitoring of similar leak-prone equipment.[173]

For ethylene oxide reductions, EPA should consider available VOC controls, including catalytic oxidizers and scrubbers.[174] For example, the ICAC explained that "there have been many advancements, in particular regarding thermal and catalytic treatment of VOC emissions" in recent years.[175] EPA should consider both alterations in the manufacturing process that could reduce the amount of VOC produced, and additional pollution controls to destroy or capture VOC emissions.[176]

In addition, in the Petroleum Refinery Sector Rule (2015), EPA recognized as a "development," the availability of fenceline monitoring technology and methods, and therefore required all facilities to implement these tools.[177] As EPA found there, the use of fenceline monitoring, such as the passive samplers or absorbent tubes EPA required using Methods 325A and 325B, reflects an up-to-date method to evaluate leaks of HAPs. There, EPA chose the chemical benzene as the analyte; but the tools EPA required for refineries can monitor for other pollutants, including chlorine, HCl, and ethylene oxide.[178] Furthermore, since 2015, there have been even further "developments" in fenceline monitoring. Local and state jurisdictions have required implementation of real-time fenceline monitoring, using various types of technology selected by the facility from approved methods, and presented for public notice and comment.

EPA would violate § 7412(d)(6) by failing to consider and account for the "developments" in fenceline monitoring, LDAR, and pollution controls here – particularly where data show significant health risks from a range of emitted pollutants, including cancer, chronic non-cancer, and acute risk. Refusing to consider these developments is also arbitrary. Chemical facilities, such as HCl facilities, are similar to refineries and other chemical plants, in their significant potential for leaks and emission spikes that cause health and safety threats, and in their complexity.

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[173] AMWA, EPA Priority: Leak Detection and Repair at 9-10, http://pubs.awma.org/flip/EM-Nov-2014/darrat.pdf (citing EPA Consent Decrees).
[174] ICAC, *Issue Brief for United States Environmental Protection Agency Administrator E. Scott Pruitt* (Aug. 2017), https://cdn.ymaws.com/www.icac.com/resource/resmgr/publications/170817_DCPD_EMD_issue_brief_.pdf.
[175] Comment by ICAC, EPA-HQ-OAR-2015-0341-0043, at 2-3 (Dec. 21, 2016), https://www.regulations.gov/document?D=EPA-HQ-OAR-2015-0341-0043.
[176] *See* ICAC *Issue Brief* at 12 (summarizing strategies for VOC control), https://cdn.ymaws.com/www.icac.com/resource/resmgr/publications/170817_DCPD_EMD_issue_brief_.pdf.
[177] EPA, Petroleum Refinery Sector, Final Rule, 80 Fed. Reg. 75,178, 75,193, 75,194 (Dec. 1, 2015).
[178] *Id.*; EPA, Fenceline Monitoring Tech. Support Document, https://www.regulations.gov/EPA-HQ-OAR-2010-0682-0210.

All of the developments discussed here are readily available, would improve emission control, reduce health risks and refusing to consider them and revise the standards to "account" for them would be unlawful and arbitrary.

VI. EPA must strengthen the compliance and enforcement provisions, including by requiring electronic reporting, and by increasing the reporting frequency, as it has proposed to do.

EPA may not lawfully or rationally finalize the proposed reporting exemption provisions (which EPA has described as extension provisions) based on Compliance and Emissions Data Reporting Interface ("CEDRI") outages or so-called "force majeure events."

A. EPA Must Not Finalize the Proposed Electronic Reporting Extension Provisions Which Are In Essence Exemptions from Compliance Reporting and Emission Standards Themselves.

EPA has proposed provisions amending these standards to allow for exemptions, described as "extensions" for electronic reporting, that should not be finalized, because these are unlawful and arbitrary for the reasons discussed below. *See* 84 Fed. Reg. at 1588.

The first part of the provision purports to allow an extension of the deadline required to submit an electronic report due to "a claim of EPA system outage" of the CEDRI, within a 5-business day time period of the deadline. 84 Fed. Reg. at 1594 (proposing § 63.9050(m)). The second part of the provision purports to allow an extension if "a force majeure event is about to occur, occurs, or has occurred or there are lingering effects from such an event" within a 5-business day time period of the deadline. *Id.* (proposing § 63.9050(n)). Neither provision sets a new firm deadline to submit the required report. Neither provision sets a firm deadline to request an extension of the reporting deadline. In each instance the proposed provision states that "[t]he decision to accept the claim . . . and allow an extension to the reporting deadline is solely within the discretion of the Administrator." *Id.* EPA proposes to create a broad definition of "force majeure event":

> For the purposes of this paragraph, a force majeure event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.*, hurricanes, earthquakes, or floods), acts of war or terrorism, or safety hazard beyond the control of the affected facility (*e.g.*, large scale power outage).

Id.

Each provision is unlawful and arbitrary because it would create a broad and vague mechanism that a facility owner or operator could use to evade binding emission standards, by evading the binding compliance reporting deadlines set to assure compliance with those standards.

The Act sets binding compliance deadlines for air toxics emission standards that EPA may not lawfully evade or extend. *See, e.g.*, 42 U.S.C. § 7412(i)(3)(A), (B) (requiring compliance dates for § 7412(d) standards "which shall provide for compliance as expeditiously as practicable, but in no event later than 3 years after the effective date of such standard," unless a 1-year extension is granted if "necessary for the installation of controls"); *id.* § 7412(f)(4) (requiring compliance by all new sources with a § 7412(f) emission standard on its effective date, and by all existing sources by 90 days after the effective date, and allowing extensions for existing sources of only up to two years after the effective date of a standard if "necessary for the installation of controls" and as long as "steps will be taken during the period of the waiver to assure that the health of persons will be protected from imminent endangerment"). EPA's proposal to extend compliance dates for reporting is an unlawful extension of emission standards, as those compliance dates are an essential part of ensuring that the emission standard is in force and compliance is assured.

The proposed extension provisions would allow sources not to meet for a period of time, or possibly ever, the regulations' firm and enforceable reporting deadlines to submit information, which are required to assure compliance with the emission standards by the deadlines set by law, as the Act requires. *See id.* § 7412(i)(3), (f)(4); *see id.* § 7412(c)(2), (d)(1)-(3). Enforceable provisions to assure continuous compliance on particular timeframes are required for emission standards. *See, e.g.*, *id*. § 7602(k) (requiring an emission standard to assure "continuous" limitation of pollutants); *id.* § 7414(a)(3) (directing that "The Administrator shall in the case of any person which is the owner or operator of a major stationary source . . . require enhanced monitoring and submission of compliance certifications"); *id.* § 7414(a)(1) (describing monitoring and reporting requirements authority). The new proposed provisions would remove the deadline for a particular reporting requirement without creating a new firm deadline. Thus, the language ("as soon as possible") removes a requirement ensuring the enforceability of the requirements and makes it likely that reporting will be significantly delayed, at best. At worst, it may lead a facility to drag its feet in submitting reports for an extended period, or ever, within a time when corrective action could and should be taken to prevent harmful and unlawful emission exceedances.

Because EPA's proposal contains no new deadline, it is not an *extension* provision, it is an *exemption*. An exemption from reporting requirements is equivalent to an unlawful exemption from the standards. As long as a facility need not report, there is no way of determining whether it is in compliance or when.

The extension provisions are also arbitrary and capricious. 42 U.S.C. § 7607(d)(9)(A). EPA gives no justification for adding these provisions showing that they are actually needed, or assessing their impact. EPA cannot make a change of this kind, even if lawful, without providing a reasoned basis, and evidence showing the actual need and value to clean air or the public interest in creating the extension provisions. There is no way in which these provisions advance public health or public welfare, and thus they are inconsistent with the Act's purpose and objectives. *Id*. § 7401(a); *see also id.* § 7412 & Senate Report of 1990 Amendments.

As an additional problem, there is simply no authority for EPA to allow any type of "force majeure event" exception or extension under the Clean Air Act. As Commenters explained in prior comments on the Refinery Rule (which was the first time EPA attempted to inject this concept into national air toxics standards), the Clean Air Act is a law enacted to protect public

health and welfare, to reduce pollution and all of the harm it causes, including cancer and other serious health impacts from hazardous air pollution, and creating a malfunction exemption contravenes the Act. *See* 2016 Comments, EPA-HQ-OAR-2010-0682-0889. The concept of "force majeure" comes from *contract law*, but the Clean Air Act is not a contract.[179] It is a binding legal requirement that facilities have no choice but to meet if they seek to emit hazardous air pollution.

EPA should not import the concept of "force majeure" into any part of the Clean Air Act. Its attempt to do so is just another variation of the prior malfunction exemptions that are unlawful under the Act, as the D.C. Circuit has repeatedly held. *See, e.g.*, *Sierra Club v. EPA*, 551 F.3d 1028 (D.C. Cir. 2008); *NRDC*, 749 F.3d at 1062-63. There is no "force majeure" exception allowed for non-compliance with the Clean Air Act or its requirements, and EPA may not create such an exemption. "The Clean Air Act and amendments thereto contain no force majeure exception." *U.S. v. Wheeling-Pittsburgh Steel Corp.*, 818 F.2d 1077, 1088 (3d Cir. 1987) (refusing to provide for a free-standing "force majeure" exception that would have exempted emission violations that fell outside the contractual term used in a consent decree due to the lack of legal basis to do so). As the D.C. Circuit explained: "After a certain point, the transgression of regulatory limits caused by 'uncontrollable acts of third parties,' such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation." *Weyerhaeuser Co. v. Costle*, 590 F.2d 1011, 1058 (D.C. Cir. 1978).

Importantly, while CEDRI outages and some events may well be out of a facility's control, facility owners and operators have many factors within their control. EPA has failed even to evaluate what steps they could and should take, for example, to predict and prevent reporting or pollution increases related to foreseeable types of events it defines as "force majeure." In the event that EPA creates a "force majeure event" extension provision, it must, at least, ensure that the facility is required to prevent similar problems in the future, and report what steps it will take in the future to prevent the same problem from recurring. When there is such a problem, the need for prompt reporting is especially important so that EPA can ensure that any actual emissions exceedances end and are corrected. Thus, allowing an unreasonable extension or not setting any deadline is especially unlawful and problematic because of the greater need for prompt reporting in the event of the type of event EPA describes, to protect public health and welfare.

Further, EPA did not even identify any problems or burdens with the electronic reporting system that could justify even a brief extension (with a firm deadline). To the contrary, in another proposed rule preamble recently, EPA stated rather that: "We note that the submission of ERT-formatted performance test and performance evaluation reports using CEDRI is fully operational, and there are no known or reported system issues … In addition, the Central Data Exchange (CDX) Helpdesk staff are available during regular business hours to support industry users in completing their submissions electronically using CEDRI." EPA, NESHAP: Petroleum Refinery

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[179] "Force majeure is a phrase coined primarily for the convenience of contracting parties wishing to describe the facts that create a contractual impossibility due to an 'Act of God.' *See* 6 A. Corbin, Corbin on Contracts, § 1324 (1962). As Corbin points out, this term is outmoded and serves no useful purpose as a test of responsibility." *Perlman v. Pioneer Limited Partnership*, 918 F.2d 1244, 1248 n.5 (5th Cir. 1990).

Sector Amendments, Proposal, 83 Fed. Reg. 15,458, 15,469 (Apr. 10, 2018). In the event that does not resolve a concern, these "are escalated to either EPA staff or the application support contractors for resolution." *Id.* Instead of finding any problems with electronic reporting, EPA found that "over 3,400 ERT files have been submitted to the EPA through CEDRI," and only 43 help calls came in, requiring escalation in only 9 instances. *Id.*

Thus, although EPA proposes extension provisions for CEDRI outages and "force majeure events," it has not based these on any actual evidence that either such event has caused any problem with electronic reporting in the past. There is no such evidence in the record provided for public notice and comment. Nor is there any evidence that if there were any reporting problem where any such event occurred, that it could not be resolved through a case-by-case resolution, or that there was any harm of any kind from not having an extension provision. On the other hand, there is a requirement for reporting on the timeframe the regulations contain, to assure compliance and achieve the health and environmental protections the regulations require. Delayed reporting and potentially a failure to report will cause harm in that it delays compliance assurance by EPA, the states, and affected community residents, and thus undermines the health and environmental protections of the standards themselves, including from harm like the cancer and the acute health threats that HCl facilities can cause. EPA's proposal is thus arbitrary because it has not given any rational basis for providing the reporting extension provisions, nor any basis for providing facilities without any hard new deadline to assure reporting indeed does occur, when there is such a strong interest in ensuring reporting *does* occur on the timeframe the regulations require.

Even if EPA had a rational basis and legal authority to allow these extensions consistent with the Act's goals, it may not create an exemption for CEDRI outages or force majeure events. At minimum, EPA must set a new firm deadline, assuring that the extension request allows only a temporary period when the facility need not report, such as a 10-day extension, rather than an open-ended extension without a deadline.

VII. CONCLUSION

For the reasons explained above, Commenters urge EPA to fully satisfy all legal requirements and protect public health in this important rulemaking for HCl facilities. EPA must address and incorporate each issue discussed in these comments, including by following the best available science and taking a health-protective approach where there is uncertainty, in order to fulfill the important regulatory duties of Clean Air Act §§ 7412(f)(2) and 7412(d)(2)-(3), (d)(6).

These comments attach sources cited as an Appendix. Commenters would be glad to provide any additional information that may be useful to EPA as it works to finalize this rule.

Commenters appreciate EPA's time and consideration of these comments. For additional information, please contact any of the above-listed Commenters, or the following people at Earthjustice: Emma Cheuse, Staff Attorney (echeuse@earthjustice.org or (202) 667-4500 ext. 5220), or Michelle Mabson, Staff Scientist (mmabson@earthjustice.org or (202) 667-4500 ext. 5254).

Appendix List

1.	Letter from Tammy Duckworth et al. to EPA Administrator Wheeler (January 29, 2019)
2.	Comments submitted to EPA from Air Alliance Houston et al, EPA-HQ-ORD-2013-0292; FRL-9807-5, 78 Fed. Reg. 25,440 (June 28, 2013)
3.	EPA, Fenceline Monitoring Technical Support Document, EPA-HQ-OAR-2010-0682 (Jan. 17, 2014)
4.	2014 National Air Toxics Assessment ("NATA"): Fact Sheet
5.	ATSDR, Chlorine Fact Sheet
6.	ATSDR, HCl Fact Sheet
7.	ACC, Ethylene Oxide Manual (May 2007)
8.	Cal. EPA, Air Toxics Hot Spots Program Guidance Manual (Feb. 2015)
9.	Cal. EPA, Air Toxics Hot Spots Program Guidance Manual - Appendices A-F (Feb. 2015)
10.	Cal. EPA, Air Toxics Hot Spots Program Guidance Manual - Appendices G-J (Feb. 2015)
11.	Cal. EPA, Air Toxics Hot Spots Program Guidance Manual - Appendix K (Feb. 2015)
12.	Cal. EPA, Air Toxics Hot Spots Program Guidance Manual - Appendices L-M (Feb. 2015)
13.	Cal. EPA, Air Toxics Hot Spots Program Guidance Manual - Appendix N (Feb. 2015)
14.	Cal. EPA, Cumulative Impacts (Dec. 2010)
15.	Cal. EPA, Technical Support Document for Cancer Potency Factors (May 2009)
16.	Cal. EPA, Technical Support Document for Cancer Potency Factors - Appendix J (May 2009)
17.	Cal. EPA, Technical Support Document for Exposure Assessment and Stochastic Analysis (Aug. 2012)
18.	ECHO Search Results, HON Subpart G
19.	ECHO Search Results, MON Subpart FFFF
20.	Testimony of Michelle Mabson, Earthjustice (March 27, 2019)
21.	Email between Emma Cheuse, Earthjustice, and Nathan Topham, EPA (April 2019)
22.	EPA, Residual Risk Report to Congress (March 1999)
23.	EPA, Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Dec. 2016)
24.	EPA, Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, Executive Summary (Dec. 2016)
25.	Sharon Lerner, "A Tale of Two Toxic Cities," The Intercept (Feb. 24, 2019)
26.	NAS, Science and Decisions: Advancing Risk Assessment (2009)
27.	NRDC, Strengthening Toxic Chemical Risk Assessments to Protect Human Health (Feb. 2012)
28.	Letter from EPA Science Advisory Board to EPA Administrator Jackson (May 7, 2010)
29.	EPA, Basic Information about the Integrated Risk Information System
30.	Cal. EPA, HCl Chronic Toxicity Summary (March 2000)

31.	Letter from Tammy Duckworth et al. to EPA Administrator Wheeler (February 13, 2019)
32.	Inaas Darrat, "EPA Priority: Leak Detection and Repair (LDAR)," Air and Waste Management Association (Nov. 2014)
33.	Jim Drago, "LDAR Programs Continue to Evolve," Environmental Protection Online (Aug. 24, 2016)
34.	Comments submitted to EPA from Earthjustice (March 22, 2016)
35.	EPA, Taking Steps to Address Emissions of Ethylene Oxide (Aug. 22, 2018)
36.	EPA, Leak Detection and Repair – Best Practices Guide (2007)
37.	EPA, Background Information on Ethylene Oxide
38.	EPA, Background and History/Chronology of Ethylene Oxide
39.	EPA, Trichloroethylene Chemical Assessment Summary
40.	EPA, Risk Management for Trichloroethylene (TCE)
41.	EPA, Memorandum - Addendum to Survey of Risks: Background Radiation (July 27, 1988)
42.	EPA, OIG Memorandum - Actions to Address Air Toxics Emissions Through EPA's Residual Risk and Technology Review Program (Dec. 17, 2018)
43.	European Chemical Industry Council, Guidelines for the Distribution of Ethylene Oxide (2013)
44.	ICAC, Issue Brief for EPA Administrator Pruitt (Aug. 2017)
45.	ICAC, White Paper: Monitoring of HCl (Jan. 2013)
46.	ICAC, Dry Sorbent Injection for Acid Gas Control (July 2016)
47.	NAS, Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues (2006)
48.	NATA 2014, National Cancer Risk by Tract and Population - Above National Average
49.	NATA 2014 Webinar (Aug. 28, 2018)
50.	Jennifer Sass, "ACC/TSCA Attack on IRIS: Formaldehyde, Chloroprene, EtO," NRDC Expert Blog
51.	Comments submitted to EPA from NRDC (March 22, 2016)
52.	Petition submitted to EPA from NRDC and Sierra Club (Jan. 14, 2009)
53.	EPA Science Advisory Board, Report on EPA Screening Methodologies to Support Risk and Technology Reviews (Sep. 13, 2018)
54.	Comments submitted to EPA from Scientists, Medical Professionals, and Environmental Health Experts (April 26, 2019)